Reimportation of Pharmaceuticals: Economic and Policy Implications

Based on a University of Michigan Center for Medication Use, Policy and Economics Internet presentation, Oct. 29–31, 2003

HIGHLIGHTS

• Differentials in International Pharmaceutical Expenditures

• Overview from the National Association of Boards of Pharmacy

• Economics and Risks of Reimported Pharmaceuticals

• Vulnerable Points in the U.S. Drug-Distribution System

• Reimportation and the Consumer

• FDA Quality Assurance and Reimportation

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WELCOME MESSAGE

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Policy Implications of Reimportation
In a Growing Market

In 2003, the Center for Medication Use, Policy, and Economics, at the University of Michigan College of Pharmacy, launched a series of invitational symposia that were intended to bring current pharmaceutical policy research to a forum comprising researchers and decision makers focusing on medication use. This supplement is derived from a symposium that specifically examined policy research with respect to the reimportation of pharmaceuticals into the United States.

Academic and nonacademic researchers who are engaged in the economics of intellectual property and innovation, as well as experts in the areas of pharmaceutical distribution channels, policies, and practices, came together for this program to share research, insights, and speculations on the public policy implications of the growing market for reimported pharmaceuticals.

The objectives of the conference were to understand the reasons for international price differences and to explore the economic and quality ramifications of increased use of reimported pharmaceuticals. Additionally, the experts gathered to examine the characteristics and trends of pharmaceuticals procured through nontraditional distribution channels. They elaborated on the dynamics of the situation and the implications of public and private policy encouraging the use of reimported pharmaceuticals. Finally, the intent of this forum was to gain an understanding about the perspectives held by various stakeholder groups including consumers, manufacturers, and payers for pharmaceutical therapies.

This supplement, which is derived from our symposium, provides me with an opportunity to share many valuable insights into this extremely complex subject. A host of respected experts present their research and opinions within these pages. Consistent with the Center’s mission and the mission of our University, we present an in-depth, objective examination of an important concept that is now being actively explored in several policy environments.
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International Pharmaceutical Expenditure Differentials: Why?

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The reimportation of prescription drugs from Canada to the United States has become a national issue prompted largely by two intersecting conditions. First, U.S. prices for some prescription drugs are higher than those in Canada; and second, a high percentage of U.S. prescription costs are not covered by insurance (CMS 2004). This burden falls most heavily on the elderly who are without prescription drug coverage.

Annual utilization of prescription drugs is approximately 32 percent less among Medicare beneficiaries who are without coverage than among those with coverage (Poisal 2001). Yet, this is only part of a larger structural difference between U.S. health care systems and the others that make up the seven industrialized nations (hereon referred to as G7): Canada, France, Germany, Italy, Japan, and the United Kingdom. For example, in G7 countries, about 76 percent of all health expenditures and 59 percent of prescription drug expenditures are publicly funded. U.S. expenditures currently are about 44 percent and 19 percent, respectively (Figure 1, page 4) (OECD 2003).

If comparisons are made beyond costs, health system differences become even more evident. The G7 countries currently spend about 9 percent of their gross domestic product on health care; the comparable U.S. figure is nearly 14 percent (Figure 2, page 4). Drug expenditure rates as a percentage of total health expenditure are reversed, with the rate in the average G7 country at 19 percent and the U.S. rate at about only 12 percent.

Figure 3 provides an overview of factors that help to explain these differences in general health care spending among the G7 countries, and pharmaceutical spending in particular. Demographics are the least likely factor to account for the differences, because the populations of the United States and other G7 countries are quite similar. A more likely explanation is social policy, which is strongly influenced by cultural expectations and medical culture. In the long run, societies cannot provide what is not economically feasible or is incompatible with social conditions. Data show that economic conditions are quite similar across G7 countries and therefore could not account for the differences. Thus, social policies are the key factors (including health care policies) that contribute to differences in health care spending.

Reimportation environment

Empirical evidence suggests that prescription drug price differences are modest; nevertheless, considerable reimportation business has developed due to several factors. Expansion of the Internet has made it easy to buy or sell virtually anything online. Also, prescription drugs have been demystified such that the public generally regards them as commodities, despite the need for a prescription. This new perspective is due mainly to direct-to-consumer advertising. Consumers tend to view the specifications of prescription drugs as standard and easy to understand. The availability of such information is perceived by consumers as an opportunity to exercise some control over their use of personal health care services. In addition, the small size of prescription drugs makes shipment by mail relatively easy and inexpensive. Finally, Americans who reimport drugs have chosen to overlook its illegality. They consider prescription drugs essential to their health and, therefore, view reimportation as justifiable. They believe the law is invalid. These factors and the absence of well-publicized negative consequences of reimportation encourage its continued growth.

Prescription drug price comparisons

Differences between the United States and other G7 countries with respect to the prices of prescription drugs are not demonstrated easily at the national level. A number of factors must be controlled when making these comparisons, such as product presentation, volume of use, and market composition. A study of pricing policies raised additional issues, including promotional costs, customer mix, patent systems, and the product development life cycle (USITC 2000).

Although aggregate price differences are difficult to demonstrate at the national level, it is easy for a consumer to compare specific drug prices in different markets. Prices at the aggregate national level may differ from those at the consumer level, because they are subject to a complex set of social policies.
Danzon has shown that volume consumed and product mix are a function of national social policy and can influence price comparisons. For example, the United States has an average of 6.7 products per molecule for cardiovascular drugs, whereas France has an average of 1.8 (Danzon 1996, 1997). Furthermore, large cross-country price differences have been demonstrated, even within the cardiovascular market (Dickson 2003). Prescription drugs are not a single market, but rather many smaller markets generally defined along therapeutic lines.

Price comparisons are complicated further because, as previously discussed, not all countries subsidize health care or pharmaceuticals to the same extent (Figure 1).

Compared with the United States, the other G7 countries have a much higher average total tax wedge (38.2 percent vs. 30.0 percent at 100 percent of the average production wage) (OECD 2000–2002). It is inappropriate, therefore, to compare prices across countries without considering the tax component differential.

**Regulatory policy**

Before a prescription drug can be marketed in the United States, it must meet stringent regulatory requirements set by the U.S. Food and Drug Administration. The time required from synthesis of a compound to FDA marketing approval for a self-originated (i.e., not licensed) new chemical entity (NCE) is about 12.8 years (DiMasi 1995). Notably, only approximately 12 percent of self-originated NCEs ever obtain marketing approval (DiMasi 2001). Most recently, the average cost of obtaining marketing approval was estimated at $802 million (DiMasi 2003). There have been lower estimates; they ignore the cost of capital, however—which is significant due to the long time needed for drug development and to receive marketing approval.

Economic risks involved in drug development are increasing in light of these regulatory issues and the introduction of the Waxman-Hatch Drug Price Competition and Patent Term Restoration Act in 1984. The dual purpose of the Waxman-Hatch Act includes restoring some patent erosion while increasing price competition through a reduction in barriers to market entry of generics. Grabowski found that within 3.5 years of a generic market entry (in 1993), generics had 71 percent of the market share (Grabowski 1996).

There is a relatively short time from marketing approval to patent expiration when costs for research and development can be recovered. For a host of reasons to be addressed in the next section, the burden falls on only a few products. In one study, the top 10 percent of products introduced between 1988 and 1992 accounted for 56 percent of all product sales (Grabowski 1990). This concentration of sales has been increasing in recent years and highlights the economic

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4 Total tax wedge is defined as combined central and subcentral government income tax plus employee and employer Social Security contribution tax, as a percentage of labor costs (excludes cash transfers).
importance of breakthrough drugs to the continued success of a pharmaceutical company. These few products support all other products for which research and development costs are not recovered. Finally, there is the problem of the recent decline in the number of NCEs approved by the FDA. Among several reasons for this decrease is the significant shift in R&D from more familiar and relatively well-understood conditions to more difficult-to-treat conditions, such as cancer and central nervous system disorders.

**Competition**

Competition within the U.S. prescription drug market has intensified, further complicating R&D cost recovery. The market for new pharmaceuticals has become so competitive that patent life no longer confers a significant monopoly. There is now competition from generically different compounds with similar therapeutic effects. For example, fluoxetine (Prozac) was approved in December 1987, and the first therapeutic competitor did not appear until 4 years later in December 1991. More recently, celecoxib (Celebrex) was approved in December 1998 and its first therapeutic competitor was approved only 5 months later, in May 1999. Although therapeutic competition is good for pricing discipline, it erodes market share for the NCE and further diminishes the time available for recovering R&D investment.

**Innovation**

These consequences of increased competition in the United States can deter pharmaceutical innovation, because funding for R&D comes from sales revenue. To the extent that sales are constrained in the United States, innovation is likely to suffer. This is because social policies generally make it difficult to increase revenue in other countries.

Costs to develop new products invariably raise the question of the social responsibility of pharmaceutical companies, because public sales are the driving force behind innovative R&D. The argument is that products generated through R&D efforts should be readily available to the American public, whose drug purchases funded the investment. On the other hand, patent policies are intended to reward innovation and encourage its continuation.

Critics have argued that the social contract with the pharmaceutical companies has become unbalanced to the extent that it has placed the public at a disadvantage. Grabowski has shown that the rate of return on pharmaceutical R&D investment is not unbalanced. Countries with strong intellectual-property protection are shown to have earlier access to a broader range of innovative pharmaceutical products than countries where protection is weak (Grabowski 2002). The final issue for many Americans is whether the burden of supporting R&D has fallen excessively on their shoulders.

**Unintended consequences**

If U.S. pharmaceutical policies were adjusted to more closely resemble the single-payer systems in the other G7 countries, a number of changes could be expected. Average prescription prices would decline, because all single-payer systems exist to constrain prices, which tends to discourage competition. The ceiling price quickly becomes the floor because there is no incentive to be lower than the maximum allowable price. French and other single-payer systems, however, have demonstrated that total expenditure is likely to increase due to induced demand, among other factors.

Reduced innovation could also be expected because there is little incentive to engage in expensive, risky, and time-consuming research. There are those who believe that pharmaceutical firms would continue to innovate because that is the basis of competition. That premise, however, does not apply to single-payer markets, because there is virtually no competition.

Although a single-payer system for prescription drugs may be unlikely in the United States, the unconstrained reimportation of prescription drugs from Canada, or elsewhere, could generate the same unintended consequences. Also, there is a limit to the savings that can be achieved from reimportation, because at some point Canadian pharmacies will not be able to meet U.S. demand. Furthermore, sufficient price differentials be-
tween products are fundamental to reimportation, and these are likely to involve only certain newly patented products. Reimportation can also be expected to be limited because it does not apply to medications for acute conditions. In addition, U.S. patients will be reluctant to reimport narrow therapeutic index products for which the consequences of errors can be severe (e.g., anticoagulants). The market for reimportation is much smaller than the total prescription drug market.

Considering that the United States is a litigious society, someone possibly will experience an adverse event due to a reimported product and seek damages. Does the U.S. consumer have standing to take legal action against a Canadian entity?

Quality issues
A law permitting reimportation was passed a few years ago, but it has not been implemented. The FDA does not have the funding necessary to ensure safety of reimported prescription drugs. Although Canadian and U.S. pharmacies and wholesalers are subject to similar rigorous regulations, it is not clear whether the definition of reimportation would include products of unknown origin (e.g., products imported into Canada from another country). It is also possible that drugs could be imported directly from countries other than Canada. Is there any reason to limit prescription drug access to Canada when another country may offer even larger savings?

Provenance of a product becomes a serious issue if quality and safety are to be ensured. The typical U.S. consumer does not have the technical expertise to determine prescription drug quality—a fact that is not lost on unscrupulous sellers.

Summary
The following questions facilitate further thought on the issue of reimportation:

Policy issues
• Who should pay for drug development?
• Do NCEs provide value for money invested?
• What is the most efficient means of developing new drugs?
• What is the proper balance between societal benefit and intellectual property protection?

Regulatory questions
• If reimportation or importation is permitted, how can the provenance of a product be protected?
• How is reimportation defined? Can a product be transported from the United States to Europe and then be sent back to the United States? Or, is reimportation a single-step process (e.g., United States to Canada and vice versa)?
• If reimportation is limited to Canada, can we expect that other countries would want to be included (or excluded) from our reimportation policy?
• Will state pharmacy practice acts be applicable to reimportation? Does reimportation alter the balance between state and federal regulations?
• If legal action occurs because of alleged harm from a reimported product, who is liable?

Market issues
• Will U.S. prices rise in protected markets to compensate for losses due to reimports?
• Will Canadians be allowed to import prescription drugs from the United States?

References
A complex phenomenon

The pharmaceutical industry and its regulators, as well as prescribers and payers, face a complex set of issues related to the potential legalization and growth of pharmaceutical reimportation in the United States. Not only are patients physically crossing borders to Canada and Mexico to purchase medications, but also proliferation of Internet access and online pharmacies has enabled reimportation to occur across the country. Those wishing to control reimportation, whether for economic, safety, case management, disease management, or other reasons, share legal and attitudinal challenges similar to those the music industry faces with the MP3 technology. There is one key difference, however: reimportation is illegal. Yet the economic incentives and the stakes of piracy are exponentially greater with prescription drugs.

At face value, the prospect of the removal of patients’ drug expenses from payers’ bottom line (when Canadian drugs are cheaper than the copayments at U.S. pharmacies) might seem attractive. Yet the unintended consequences wrought by losing the ability to monitor compliance and comorbidities quickly end such fleeting economic benefit. Recently publicized incidences of prescription drug counterfeiting and the related potential for other malicious tampering are also important risks to consider. Despite the apparent risks, consumers have responded to the incentives to buy pharmaceuticals outside the United States, and the incidence of reimportation continues to rise. Reimportation also is fueled by the significant size of the uninsured population (43 million per the 2000 U.S. Census) who would pay for medications out of pocket and at much higher prices.

Growth resilient but not immune

In the third quarter of 2003, the number of prescription drug sales through Internet pharmacies increased by 35 percent, and overall growth is projected to exceed 143 percent compared to fiscal year 2002. Physical reimportation in border states, such as Michigan and New York, was likewise 13 percent higher in the third quarter of 2003, and estimates project overall growth of 18 percent compared to the previous year. The combined Internet and foot traffic full-year forecast put reimportation sales just under $700 million.

Looking solely at the Canadian market, the number of confirmed Internet pharmacies totaled 48 as of March 2003 (up from 35 as of December 2002); unconfirmed Internet pharmacies totaled 51 (up from 43 as of December 2002). As of October 2003, the confirmed count increased to 79 and the unconfirmed count to 114, a clear sign that the reimportation trend continues to accelerate. The province of Manitoba has the largest concentration of Internet pharmacies, accounting for about 43 percent of all Canadian outlets. Nevertheless, the explosive growth is starting to slow down, as evidenced by Internet pharmacy sales-volume growth that declined from more than 100 percent in the second quarter of 2002 to less than 10 percent in the second quarter of 2003.

The cardiovascular category accounts for 15.4 percent of sales from Canada to the United States (not including foot traffic), and the cholesterol-reducing category accounts for 17.8 percent. Among Internet pharmacies, gastrointestinal products, cardiovascular products, and statins led growth with 73 percent, 60 percent, and 55 percent, respectively (growth based on a comparison of the first quarter of 2003 and the final quarter of 2002).
of 2002 vs. the second and third quarters of 2002). These growth rates dwarf the overall Canadian market growth in the same categories (9, 5, and 9 percent growth, respectively), reflecting the impact of cross-border sales through the Internet (Figure 1, page 7).

Alternatively, we see foot traffic, identified by comparing sales-per-capita volume between border region (40 miles from the border) and nonborder region outlets (60 miles from the border), edging back up. It has changed from a low to a high trend between the first and second quarters of 2003, possibly due to Internet pharmacy regulation and changes in the degree of security on the U.S.-Canadian border.

Four manufacturers have taken action to curtail reimportation, particularly through Internet pharmacies. GlaxoSmithKline (GSK) was the first to intervene (January 2003), and Canadian Internet pharmacy sales subsequently dropped significantly. Neither AstraZeneca’s intervention (April 2003) nor Wyeth’s (June 2003) led to immediate significant sales declines, and Pfizer’s intervention (August 2003) came on the heels of the first downward trend since the GSK fallout. The combined effects of all four manufacturers seem to have a plateau effect on the overall sales to the United States, as shown in Figure 2. Furthermore, Eli Lilly instituted similar supply restrictions last October. This may result in additional slowing of the trend.

Understanding purchasing behaviors
Although reimportation trends are not immune to manufacturer and regulatory or legal interventions, the trend continues to grow. The resilience of the trend with respect to purchasing behaviors and general public awareness of the issue was addressed in an IMS survey.

Undoubtedly, many would presume that concerns regarding both the safety and legality of the practice serve as significant barriers to reimportation of prescriptions. Nevertheless, findings generated from IMS’s 2003 telephone survey contradict that assumption. Six hundred U.S. residents 18 years or older who lived more than 100 miles from respective borders and filled at least two prescriptions in the past 6 months participated.

Awareness of safety concerns was high overall (72 percent), with the greatest awareness in older groups (84 percent among those 65 to 74 years old, 83 percent among those 75 to 84 years old). Relative concerns about safety were low, however. Respondents were split evenly with respect to the safety issue for purchasing prescriptions from pharmacies outside the United States (37 percent believe it to be safe; 35 percent believe it to be unsafe). Seventy-five percent of respondents likely to purchase prescription drugs outside the United States believe it to be safe for individuals to do so; 40 percent of those less likely to engage in cross-border activity believe the practice is not safe.

When asked about perceptions regarding the practice’s legality, 45 percent of the same 600 respondents think that the practice is legal, and 33 percent are unsure. Perception of legality (59 percent) is much stronger among those likely to purchase prescriptions outside the United States. Even among those less likely to purchase outside the United States, however, 42 percent think that the practice is legal.

Details regarding actual purchasing behavior are even more telling than general public perceptions of the practice. Of survey respondents, 4 percent indicated that they had purchased prescriptions outside the United States in the past 12 months, and 3 percent indicated that they had purchased outside the country in the 12 months prior to that. These figures are lower (7 percent) than those reported by the Wall Street Journal Online Harris Interactive Health Care Poll that was released in October 2003. Nevertheless, the survey findings also indicated that 16 percent of respondents are likely or very likely to purchase outside the United States.

Most surprisingly, of those who had purchased prescriptions outside the United States, more than half (62 percent) had prescription drug coverage (Figure 3). Five percent, however, purchased contraceptives (often not covered by benefit plans) and 9 percent purchased pain medications (non-narcotics can be purchased in Mexico without a prescription). Furthermore, among the general public, the likelihood of buying prescriptions outside the United States did not vary greatly among those with or with-
out drug coverage (15 percent vs. 20 percent likelihood, respectively). Thus, it is reasonable to hypothesize that patients with some health coverage still may be inclined to buy prescriptions from outside the country when faced with high copayments and annual deductibles.

Somewhat less surprising, however, were findings confirming that in the general public, age, lower-income levels, and use of multiple drugs were key drivers of the likelihood of purchasing prescription outside the United States. Respondents in the 45-to-54 and 65-to-74 age groups were more likely (24 and 22 percent, respectively) to purchase prescriptions outside the United States; the 25-to-34 age group was least likely (2 percent). Additionally, a greater proportion of respondents in the lower-income groups (26 percent of those earning less than $19,000 per year) were more likely to fill a prescription outside the United States, compared to the higher-income groups (8 percent of those earning $60,000 to $99,000 per annum). Finally, those taking multiple prescriptions were somewhat more likely to reimport prescriptions than those taking only one or no prescriptions regularly (18 percent for those taking two to three prescriptions, 19 percent for those taking four to five, and 18 percent for those taking six or more, compared to 12 percent of those with no regular prescriptions and 8 percent of those taking just one).

Conclusion
Reimportation volume still is growing rapidly. Nevertheless, interventions are starting to slow the rate of growth. Of the prescription-taking public, 4 to 7 percent has practiced reimportation, with the potential for that number to grow to about 16 percent. Issues of safety and legality are not slowing down reimportation.

Patient characteristics of age (older), income (low) and concomitant medications (added cost) are more closely associated with reimportation. Surprisingly, prescription drug benefit coverage is not a factor. Nevertheless, these findings could change depending on Medicare drug benefit legislation provisions on reimbursement and reimportation (pending execution) plus any initiatives to provide prescription drug coverage to the uninsured. Furthermore, state actions on reimportation, such as New Hampshire’s intent to import prescriptions from Canada, may affect the overall trend.

Additional market factors, including average wholesale price reform and generic drug legislation, likely will further complicate the overall issue of pharmaceutical reimportation. For now, all stakeholders — health care consumers, physicians, pharmaceutical companies, as well as federal, state, and local governments — continue to grapple with this complex issue and its impact on the entire health care landscape.
Historically, pharmaceutical prices have varied significantly across countries. This wide range of costs provides an incentive for arbitrage, a mechanism for sidestepping the secure supply chain and high prices that characterize some markets. Given that parallel trade in pharmaceuticals circumvents the regulatory protocols of the U.S. Food and Drug Administration, reimported drugs carry an increased risk of counterfeiting. This article examines the economic dynamics of reimportation and the risks posed by counterfeit pharmaceuticals. The analysis addresses the economic incentives, public policy ramifications, quality implications, and several policy alternatives.

Proposed solution to rising costs

The market for pharmaceuticals is characterized by sizable price differences across countries, which reflect distinct demand patterns, as well as differences in governmental regulations and health care policies. Recent events have drawn attention to the pharmaceutical price differential between the United States and Canada. In 2002, “Drug prices in the United States were 67 percent higher than in Canada” (Harris 2003). Reimportation, or parallel trade, has been proposed as a solution, allowing American consumers to purchase drugs at lower Canadian prices.1 Under current U.S. law, it is illegal to import prescription drugs from other countries. Nevertheless, cross-border prescription drug sales have increased tremendously. Recent estimates place the value of such sales from Canada at $650 million a year (Harris 2003). A similar trend has emerged along the U.S.-Mexican border.

To understand parallel trade, it is necessary to understand pharmaceutical price discrimination. The pharmaceutical industry is characterized by a high research and development cost that must be shared by all markets. Economic theory holds that the most efficient mechanism2 for recovering this shared cost is to charge different consumers different prices, based on price sensitivity, to obtain the set of prices that generates revenue sufficient to cover the shared R&D cost as well as the highest level of consumer welfare.

Parallel trade results in unregulated distribution pipelines and weakened regulatory control of the supply chain, both of which are characteristics that facilitate counterfeiting. According to the World Health Organization, counterfeiting is facilitated when “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is a lack of effective intellectual property protection; and due regard is not paid to quality assurance” (WHO 1992). Notably, many characteristics described by the WHO are exacerbated in markets in which reimportation occurs.

Magnitude of the problem

According to the WHO, “A counterfeit medicine is one [that] is deliberately and fraudulently mislabeled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products, and counterfeit products may include products with correct ingredients, with wrong ingredients, without active ingredients, with incorrect quantity of the active ingredient, or with fake packaging” (WHO 1997). It is a pervasive problem, affecting nations of every size and income level, and drugs of every description. Nevertheless, the magnitude of the problem is difficult to estimate. The following facts illuminate the problem’s scope:

• Counterfeit aspirin tablets containing little or no acetylsalicylic acid can be profitable, especially at open-air markets, such as those in African villages (McGregor 1997).
• In Nigeria, 80,000 children have been given fraudulent meningitis vaccines. India has been found to have some fake polio vaccines (Knox 2003).
• India accounts for 35 percent of the counterfeit drugs that are produced; Nigeria produces about 23 percent; and Pakistan, 13.3 percent (Datta 2003).
• Dora Nkem Akunyili, PhD, head of Nigeria’s institutional equivalent of the FDA, has stated that the share of counterfeit drugs in her country may be as high as 90 percent (Kontnik 2003).

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1 “Parallel imports are legitimately produced goods imported legally into a country without the authorization of a trademark, copyright, or patent holder. The essential purpose of such trade is arbitrage between countries with different prices” (Ganslandt 2001).
2 This mechanism, known as Ramsey pricing, provides the way in which markups should vary based on elasticities of demand.
While pharmaceutical counterfeiting is as profitable as the narcotics trade, it is subject to lesser criminal penalties. It also is a difficult crime to uncover, even with the availability of sophisticated tools to assist in this process. Predictably, criminal syndicates in all regions of the world have established a visible presence in the counterfeit pharmaceuticals trade.

The WHO estimates that 10 percent of the global market for pharmaceuticals comprises counterfeit products. With an estimated annual turnover of $435 billion, the financial loss for the industry could reach $43.5 billion per year. To put this figure in perspective, it is worth noting that member companies of the Pharmaceutical Research and Manufacturers of America invested $32.1 billion in R&D in 2002 (PhRMA 2003).

### Public policy ramifications

Beyond arbitrage, there are long-term consequences for pharmaceutical prices due to reimportation. In the long run, it is more likely that prices will rise in Canada rather than decrease in the United States. Evidence of this strategy already is visible in the single market of the European Union (Danzon 1998).

Alternatively, pharmaceutical manufacturers may decide to limit the supply of drugs to source countries. Considering that the U.S. market is 10 times larger than the Canadian market, many manufacturers, including GlaxoSmithKline, Pfizer, AstraZeneca, and Wyeth, are electing to limit drug sales to Canada to curb reimportation. Manufacturers now are selling their products directly to pharmacies and hospitals instead of going through wholesalers or distributors, allowing them to enforce their terms of sale more effectively.

Although prices are the driving force behind reimportation, they are only part of the problem. The economic welfare effects generated by parallel trade are ambiguous, further complicating the analysis. As with patents, parallel imports involve a tradeoff between rewarding innovation and market power. The ultimate value of the patent depends, in part, on the geographic reach of this protection. Parallel imports may reduce the patent holder’s ability to capture returns to R&D, thus potentially diminishing the incentive to innovate. Ultimately, pharmaceutical reimportation may decrease global welfare.

The incentive to invest in R&D is the third public policy consideration. While estimating drug development cost is controversial, it is undeniably an expensive undertaking. According to the Tufts Center for the Study of Drug Development, the estimated cost is nearly $900 million (Tufts 2003). As such, it is not surprising that patent protection is disproportionately more important in the pharmaceutical and chemical industries than in other sectors. It ensures that the researcher appropriates the returns to R&D. Patents and other forms of protecting intellectual property rights safeguard the industry’s ongoing investment in R&D. This protection is undermined by price controls that prevent innovative firms from recovering their research investments. The decline of the European pharmaceutical industry is evidence of the effects of price controls.

Finally, parallel imports preclude the FDA from guaranteeing the safety of drugs that arrive from importing nations. Without a secure supply chain, the FDA’s capacity to oversee the situation is compromised and its responsibilities become unmanageable. Providing safety assurances for reimported drugs would necessitate monitoring not only the Canadian supply chain, but also the global pharmaceutical supply chain. Legalizing parallel trade in pharmaceuticals from Canada permits drugs to come from any nation or source, as long as they enter the United States through Canada.

### Quality implications

Because many reimported prescription drugs are genuine, reimportation is a necessary but not sufficient condition for quality assurance. Storage and handling conditions are also concerns. Other countries may not adhere to the same rigorous standards that the FDA mandates. The strict chain of custody maintained by firms and required by the FDA may be compromised, resulting in subpotent drugs. The existing United States regulatory system safeguards not only the pharmaceutical source, but the handling conditions as well.

Although precise estimates do not exist, the use of counterfeit pharmaceuticals has resulted in prolonged illness, debilitation, and death—a phenomenon not limited to developing nations. Reimported drugs from Mexico already have been linked to several deaths in the United States (Turner 2003). Moreover, counterfeit drugs that contain a substantially reduced dose of the active constituent contribute to the great increase in global drug resistance, undermining the fight against infectious diseases.

If the U.S. market were to be opened to reimported prescription drugs, the security of the existing system could not be relied on to protect the consumer. The

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5 Echoing earlier findings, the 1994 Carnegie-Mellon Survey found that while patents are seen as “the least effective of the appropriability mechanisms,” the drug industry regards them as more effective than other mechanisms (Cohen 1996). Several additional studies report that the protection of intellectual property is disproportionately more important to the chemical and pharmaceutical industries. For a comprehensive review of these studies, refer to Lybecker 2000.
FDA’s regulatory system is based on the incentives of stakeholders who have much to lose if they fail to play by the rules. The current system, therefore, is ineffective when it comes to rogue traders who have little to lose and frequently operate at the market fringe (deKieffer 2003). The threat of rogue traders is only one risk of reimportation, which has led to widespread opposition among regulators and health care professionals. FDA opposition to pharmaceutical reimportation dates back to 1969 — 10 of the last 11 FDA Commissioners have opposed the policy. In addition, both former Health and Human Services Secretary Donna Shalala and current HHS Secretary Tommy Thompson have expressed their opposition.

Safety concerns surrounding pharmaceutical reimportation also alarm international authorities. Because the population of the United States is nearly 10 times that of Canada, Canadian officials refuse to monitor drugs shipped to the United States or to stop the huge flow of drugs moving through Canada into the United States from other nations. Moreover, legislation now under debate in Congress provides that covered products may be imported from more than 24 nations.

Finally, parallel trade in pharmaceuticals generates a number of monitoring difficulties that are less apparent but significant threats to safety. With drugs entering through many source-nations, safety warnings and product recalls are more difficult to execute. In addition, product-packaging standards vary across markets, and prescription recommendations and contraindications also may differ. Differences in product packages remove the familiar packaging clues that are so important in the visual detection of counterfeits.

Policy alternatives

Consumers want access to a variety of affordable, safe, innovative prescription drugs without prohibitively high prices, counterfeit drugs, diminished R&D, or burdensome government regulation. How to ensure this access and avoid the undesirable elements is much less clear. The following four possible policy alternatives are proposed as a starting point:

- Health insurance and prescription drug coverage. The primary focus of the current debate has been the elderly in the population who are without prescription drug coverage. The best solution will address the underlying problem by securing an affordable health care system.
- Manufacturer’s rebates. This alternative would require pharmaceutical manufacturers to change their pricing policies in existing low-price countries. Prices would increase to a uniform price level, but manufacturers would offer rebates that would be paid to the payer or national health system.
- Reimportation exemptions. Considering the economic efficiency of Ramsey pricing, reimportation should be disallowed for products such as pharmaceuticals that incur significant global shared costs. Exemptions to parallel trade laws would allow manufacturers a short period of above-marginal-cost pricing to recover the R&D investment.
- Free market exports. Drugs consumed domestically in low-price countries would be subject to government price controls, while exported products would be priced according to market forces. It should be possible to institute this pricing policy through contractual agreements between manufacturers and suppliers.

Price differentiation vs. safety concerns

At first glance, parallel trade in pharmaceuticals appears to be the solution to rising drug prices. Yet the price differential that characterizes neighboring markets and safety concerns actually are the most important elements of the current debate. While capitalizing on international price differences is tempting, the economic incentives involved in pharmaceutical reimportation cannot be considered without the associated risks. Before embracing reimportation, the public policy ramifications, quality implications, and potential policy alternatives should be considered. In summary, reimportation is a complicated issue that has the potential to shape both health care policy and the state of the pharmaceutical industry.

References

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6 Pharmaceutical manufacturers, wholesalers, distributors, physicians, and pharmacists.
8 The complete list of importing countries may be found in the United States Code, 21 USC 382(b)(1)(A).


Pharmaceuticals are indispensable to health systems; they complement other types of health care services to reduce morbidity and mortality rates and enhance quality of life. Used appropriately, they have the power to make our lives longer and qualitatively better. This is particularly true for the elderly, who are often faced with chronic health conditions that necessitate continuous pharmaceutical consumption. The moral dilemma for policy makers then becomes a question of whether individuals have an inalienable right to pharmaceutical access.

Canadian Internet pharmacies and the ongoing debate

Whether the American consumer has an inalienable right to obtain medications underlies much of the debate among U.S. policy makers regarding drug purchases from Canadian Internet pharmacies. Such sales are estimated to be as high as 650 million dollars a year — an amount attributable, at least in part, to the aging of the U.S. population, high drug prices in the U.S. pharmaceutical free market that lacks price controls, and the limited drug coverage in the United States under public and private health insurance plans (Cohen 2003).

Despite its potential illegality, recognized or unrecognized, the practice of buying pharmaceuticals from Canada is viewed favorably by most Americans. A Wall Street Journal Online/Harris Interactive Health Care Poll, in Oct. 2003, found that 77 percent of Americans surveyed deem it unreasonable for pharmaceutical companies to stop Canadian pharmacies from selling drugs to Americans over the Internet (Lamb 2003). U.S. politicians have demonstrated overwhelming support for cross-border purchases due to the political capital these issues generate. It has become an issue that has the support of all parties in Congress (Sanders 1999). For example, Minnesota Republican Rep. Gil Gutknecht said the FDA is trying “to undermine a legislative initiative the American people desperately want and need,” in reference to the drug reimportation bill that he sponsored (PBS 2003).

Price regulation and drug coverage: United States vs. Canada

The consequences for Canada of U.S. pharmaceutical policies of omission have included no price regulations; and, until the recent reform by President Bush, an absence of prescription drug coverage under Medicare. As much as 35 percent of Medicare beneficiaries do not have drug benefits (Families USA 2002). It is questionable, therefore, how effectively the new legislation will diminish Internet pharmaceutical purchases from Canada.

The Congressional Budget Office (CBO) projects that rising drug prices will continue to assume a large percentage of the income of seniors. Furthermore, the CBO estimates that from 2004 through 2013, spending for prescription drugs by and for the Medicare population will total roughly $1.8 trillion, or nearly 50 percent of the projected $3.9 trillion in Medicare outlays over the same period (CBO 2003).

In contrast, Canada provides pharmaceutical coverage for seniors and other specified groups (e.g., native Canadians, disabled persons, and the poor). The federal Patented Medicines Prices Review Board (PMPRB) was established in 1987 to ensure that costs of patented drugs in Canada are not excessive. In addition, provincial and territorial governments regulate prices of drugs that are available on their formulary through programs such as the Ontario Drug Benefit Program. Drug pricing regulations and a weaker Canadian dollar have contributed to pharmaceutical prices in Canada that are much lower than those in the United States. Although Canadian drug prices are not low by international standards, they are more or less consistent with drug prices in other jurisdictions. According to the PMPRB, 2002 prices in the Canadian market were approximately only 1 percent higher than median foreign prices (PMPRB 2002).

The U.S. government’s failure to provide pharmaceutical coverage for Americans, particularly for the elderly, has heavy repercussions politically. For Americans 65 and older, health care was among the high-priority issues that decided congressional votes in the last election. Recognizing this, the House of Representatives passed the Pharmaceutical Market Access Act, HR 2427, in July 2003, to allow individuals, pharmacists, and wholesalers to import U.S.-manufactured drugs from Canada and 24 other countries. The CBO estimates that from 2004 to 2013, this legislation, if enacted, would reduce total U.S. prescription drug expenditures by approximately 1 percent, or $40 billion (CBO 2003).

Canadian reaction

Public reaction among Canadians to cross-border pharmaceutical purchases has been less salient. Some
Canadians, particularly in Manitoba, view Internet pharmacies positively, considering what they contribute to the economy and the high financial incentives they offer participants in the business. In contrast, health professionals, brick-and-mortar pharmacies, pharmacy regulatory bodies, and other stakeholders often view the Internet phenomenon as an unsavory threat to the integrity of Canada’s pharmaceutical system (CPhA 2003).

The Canadian Pharmacists Association (CPhA) states that it does not support the international purchase of pharmaceuticals through the Internet, because such commerce: 1) compromises the relationship between the patient and the health care professional; 2) presents a credible threat to the drug supply and level of Canadian drug prices; and 3) violates local and international laws. In the CPhA Statement on International Prescription Services and Distance Provision of Pharmaceuticals, it is emphasized that the public protection safety net can be bypassed by purchasing pharmaceuticals through the Internet (CPhA 2003).

Internet pharmacies place financial stress on other retail pharmacies, because they offer significantly higher wages to pharmacists. To stop the flow of pharmacists to Internet pharmacies from retail pharmacies, traditional retailers have had to offer dramatic wage increases. Although this may not be viewed as a negative outcome for some, it may promote the closing of small pharmacies that are unable to compete with the wages of the Internet entrepreneurs.

In addition, the rush of much-needed pharmacists into the Internet trade has undeniably created some additional pressures on Canada’s health care system, particularly in Manitoba, where the Internet pharmacy industry is robust. The number of pharmacists serving Canadians has been reduced, and those who remain in traditional pharmacies face greater demands (Rx & D Canada 2003). The drug shortages that many cite as an outcome of this phenomenon are not at crisis levels; IMS Health estimates that 4 percent of the Canadian market is coming into the United States (Long 2004). As a result of the Internet pharmacy business, however, pharmacists often spend more time trying to source pharmaceuticals than they do carrying out more productive work, such as patient consultation. These issues raise the question: How can Internet pharmacies be regulated more effectively?

**Government’s role**

Part of the conundrum surrounding the business of Internet pharmacies can be attributed to the operators selling drugs across borders who are challenging established standards of practice, legislation, and regulation. They weave their way around and through norms, placing into question the role of government in drug regulation. Considering the specialized therapeutic and curative properties of pharmaceuticals, governments have an accepted core responsibility to ensure that pharmaceuticals are of good quality and effective.

While provincial governments in Canada and state governments in the United States regulate pharmacies and pharmacists, Internet pharmacies generate regulatory confusion because they move products between jurisdictional boundaries—provincial, state, national, and international.

Preventing Internet pharmacy sales from flowing across jurisdictional borders will necessitate cooperation from both sides of the border and novel forms of regulation. The United States and Canada must assist each other if serious governance changes are going to occur.

**Obstacles to resolution**

To address the need for cooperation between the United States and Canada, the FDA and Health Canada signed a memorandum of understanding in November 2003, calling for the agencies to share information concerning the reimportation of pharmaceuticals manufactured in the United States (Health Canada 2003). Nonetheless, the FDA and Health Canada soon became embroiled in a debate about the quality of drugs from Canada and institutional responsibility.

Further complicating efforts being made to resolve the problem is the likelihood that any government response, particularly from the United States, will have to contend with public contest. Politicians and many other public figures have lauded pharmaceutical reimportation, as noted earlier. For example, William D. Novelli, the executive director and CEO of the AARP, a powerful lobby group, wrote in a 2003 letter to two members of Congress that while not a panacea for soaring drug costs, reimportation could place downward pressure on the double-digit increases in costs that Americans face each year (Novelli 2003).

Rod Blagojevich, the Democratic governor of Illinois, supported an October 2003 report on reimportation of drugs for state employees and retirees, which notes that an annual cost savings of $90 million could be realized if drugs are purchased in Canada (Kamath 2003). Mayor Michael Albano of Springfield, Mass., made nationwide headlines in July 2003 for his program to encourage the importation of drugs from Canada for city employees and retirees, for which he cites annual savings of $4 million to $9 million (Dorning 2002).

International pharmaceutical companies, such as GlaxoSmithKline (GSK), Pfizer, AstraZeneca, and Wyeth, have responded to a perceived failure of governments to regulate Internet pharmacy purchases by changing how they distribute their products for sale in Canada. For example, since January 2003, these companies have limited the supply or stopped the sale of drugs to Internet pharmacies to preclude the flow of their products from
Canada into the United States. Specifically, in January 2003, GSK publicized its intent to stop selling to Canadian pharmacies that sell to Americans over the Internet. In August 2003, Pfizer notified 50 Canadian pharmacies that they would have to order their drugs directly through the company and also limited the sale of its products from Canada to the United States.

**Stronger FDA role**

The fallout from cross-border purchases has compelled the FDA to strengthen enforcement relative to imported Canadian drugs, focusing its efforts on institutions such as distributors and Internet pharmacies. On Sept. 16, 2003, the FDA issued a warning to Ontario-based CanaRx Services, which provides drugs for the program encouraging importation in Springfield, Mass., stating that the company’s operations are illegal. The FDA’s outgoing commissioner, Mark McClellan, MD, PhD, stated, “Our investigation has shown that CanaRx operates a drug-purchasing arrangement that channels drugs through companies other than licensed pharmacies and does not consistently use shipping practices that ensure its drugs are safe and effective” (FDA News 2003).

The FDA also plans to review and revise its policies on prescription drug packaging and distribution in response to concerns about counterfeit medications. Nevertheless, there are obstacles that will mitigate the success of the FDA in preventing the importation of Canadian pharmaceuticals into the United States. It faces the challenges presented by limited human resources and the cold reality that borders are porous despite how tightly they are monitored.

Whether cross-border pharmaceutical purchases subside in the near future will be determined by the extent to which cooperation can be achieved on both sides of the border and across all levels of government. Canadians are beginning to question the value of the phenomenon in terms of their health care system and may call for quick government action to outlaw or severely restrict the practice.

In the United States, the FDA recently adopted a regulation that will speed the entry of generic versions of select prescription drugs into the market, which may help to increase the affordability of some products. Finally, the Medicare reform that was passed recently may slow cross-border Internet pharmaceutical sales. Only time will reveal whether these initiatives will bring us closer to a resolution that limits breaches of legislation and regulations but ensures that Americans have better access to essential medicines.

**References**


A growing number of U.S. state and municipal governments seek to import Canadian prescription drugs to reduce their drug plan costs. Canada's drug prices are lower than those in the United States, primarily due to Canada's government-imposed price controls. Lower costs in Canada also can be attributed to the differences between the two countries with respect to exchange rates and product liability laws. Through the Prescription Drug Marketing Act of 1988, Congress banned the reimportation of U.S.-made prescription drugs to prevent potentially unsafe repackaging and to minimize exposure to counterfeit products. Only medications for approved emergency care, those reimported by original manufacturers, and those imported in small quantities for personal use are exempt. Through the personal-use exemption, large Canadian mail order distribution networks, often operating through the Internet, are generating substantial profits. They achieve these profits by being allowed to charge significantly higher markups on Canadian prescription drugs sold to Americans than they are allowed to charge Canadians under Canadian federal and provincial drug-pricing regulations.

This practice presents a number of serious challenges for Canadian as well as U.S. policy makers. For Canadians, exportation of their prescription drugs jeopardizes patient access to drugs as supplies are diverted to the U.S. market; encourages unethical practices by pharmacists and physicians who prescribe and dispense prescription drugs to patients they have never seen; and entices community and hospital pharmacists to abandon their community or hospital practices to participate in this questionable but profitable business. For U.S. and Canadian governments, exportation impedes their ability to ensure the safety of their respective drug supply systems.

There is an interesting aspect to the proliferation of schemes to import prescription drugs into the United States; it is the extent to which otherwise responsible U.S. legislators ignore the concerns that existing legislation is intended to address. In fact, many elected officials make misleading claims that drugs imported from Canada are either approved by the U.S. Food and Drug Administration or are otherwise subject to the protection of Canada's regulated drug approval and distribution system. For instance, advocates of importing drugs from Canada often claim that products imported by the United States are reimported U.S. drugs or FDA-approved drugs. The fact is, however, only drug manufacturers or their agents can import Canadian manufactured drugs approved by the FDA for the U.S. market. These drugs carry U.S. prices, because they are not subject to Canadian price controls.

Safety of drug supply chains

The FDA and the Health Products and Food Branch (HPFB) in Canada, the agencies responsible for the safety as well as approval, supply, and distribution of prescription drugs, are unable to attest to the safety of drugs imported outside of the regulated distribution system. In May 2003, in a letter to the Washington Post, Canada's assistant deputy minister of health, Diane Gorman, asserted that Canada cannot vouch for the safety of drugs imported into the United States (Kaufmann 2003). Gorman confirmed: “Importing countries — in this case, the United States — are responsible for ensuring that drugs meet their regulatory requirements” (Gorman 2003). Her U.S. counterpart, William K. Hubbard, senior associate commissioner of the FDA, echoed the lack of responsibility for foreign drug supplies in his testimony before the Senate Committee on Commerce, Science, and Transportation in September 2001. “A growing number of Americans are obtaining their prescription medications from foreign locations,” said Hubbard. “They often seek out Canadian suppliers or sources that purport to be Canadian. As we have said in the past, the FDA cannot ensure the safety of drugs purchased from foreign sources” (Hubbard 2001).

Advocates of importing prescription drugs from Canada into the United States dismiss any safety concerns this may raise, by pointing to the highly regulated approval, supply, and distribution of prescription drugs in Canada. Furthermore, they ignore the ability of those who sell drugs through the Internet to evade the drug submission, approval, and distribution regulations of Canada and the United States. They also ignore that drugs either manufactured in Canada or imported from other countries into Canada for exportation are exempted from Canadian regulatory oversight. Section 37 of the Canadian Food and Drugs Act states: “This Act does not apply to any packaged food, drug, cosmetic, or device not manufactured for consumption in Canada and not sold for consumption in Canada”(Dept. of Justice 2003).

In Canada, the federal government is responsible for the safety and efficacy of the drug supply system. It ful-

Economic and Policy Implications Of Reimportation: A Canadian Perspective

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The fact is, however, only drug manufacturers or their...
fills this responsibility through the regulations that cover nearly all aspects of the drug supply chain, including new drug submissions and approvals; safe packaging and labeling requirements; wholesale and import licensing; limitations on marketing and promotional activities; and mechanisms for reporting postmarketing adverse reactions. There are records of prescribed drugs and recall mechanisms to remove any drug from distribution found to have unanticipated adverse effects or defects. Strict packaging and labeling requirements are also enforced. The provinces provide additional protection for drug consumers by regulating the standards for safe prescribing and dispensing of prescription drugs. The importation of pharmaceuticals, under the personal-use exemption through mail order and often the Internet, circumvents all the above safeguards.

It is likely that Canadians are confident in the safety of drugs that are legally distributed and sold through Canada’s regulated drug supply. Yet even Canada’s HPFB has warned its own citizens about the dangers of foreign suppliers who use the personal-use exemption, such as the Internet drug sellers, to ship Canadian drugs to the United States. “The personal-use exemption unfortunately provides an opportunity for these suppliers to conduct commercial activities and to evade the submission review process for individual products, and/or the Establishment License requirements for importers, by supplying their drug products primarily through the mail to individual Canadians…. This has ramifications related to safety, because large quantities of products, which have not been reviewed for safety and/or efficacy, and which are of unknown quality, can enter the country and be distributed. The lack of an importer also means no person is responsible for meeting GMP (good manufacturing practice) standards or other requirements, such as appropriate record retention or recall mechanisms” (Health Products 2002).

Despite the similar high manufacturing standards upheld in Canada and the United States, the assumption that drugs marketed in Canada are identical to those in the United States is flawed. There are often important differences in formulation and manufacturing processes. Canadian prescription drug labeling and prescribing information are never identical to that in the United States. Furthermore, concerns about safety increase with the prospect that many drugs making their way from Canadian suppliers to U.S. consumers are neither of Canadian nor U.S. origin.

According to Industry Canada data, between January and August of 2002 and between January and August of 2003, pharmaceutical/medicinal product imports into Canada increased 24 percent. Although the United States remains the primary source of Canadian drug imports, the percentage of total Canadian imports from the United States since 1998 has been dropping; it fell from 60 percent in 1998 to 48 percent in 2002. Imports of drugs to Canada from countries other than the United States are increasing, however. More than 95 percent of Canadian imports in 2002 came from the United States and 18 Western European countries with which Canada has federally negotiated mutual recognition agreements (MRAs) about pharmaceutical GMPs. Yet there are almost $400 million worth of imports from countries without MRAs. In fact, though Canada has MRAs with only the United States and 18 Western European countries, 36 countries exported $500,000 or more in drugs to Canada during the 12-month period ending August 2003. During this same period, imports from China to Canada increased by more than 38 percent; imports from South Africa increased 98 percent; from Ecuador, 292 percent; from Argentina, 176 percent; and from Iran, 327 percent (Trade Data 2003).

As the end consumers in this drug-importation chain, Americans have to deal with the safety issues that arise with unregulated importation. Recent FDA spot checks at U.S. mail facilities revealed that nearly 90 percent of mail order imported drugs coming into the United States were unapproved products. In a 2001 pilot project in Carson, Calif., it was determined that less than 4 percent of the intended recipients had valid prescriptions, and that drugs not approved by the FDA or removed from the market for safety reasons were making their way into the hands of consumers, as were drugs with serious contraindications and interactions (FDA 2003).

Effect on Canadian patients and consumers

Unregulated exports and imports through Internet pharmacies in Canada are making it increasingly difficult to ensure the adequate supply of drugs for Canadian patients. They are generating enormous profits for a small group of entrepreneurs at the expense of Canadian patients. Canada accounts for approximately 2 percent of world pharmaceutical sales. In contrast, the U.S. market accounts for nearly 50 percent of global drug sales. There simply are not enough prescription drugs available from Canada to meet the demands of the U.S. market (see Figure). Even the Canadian International Pharmacy Association (CIPA) that represents Canadian Internet drug sellers acknowledges that the demands of municipal and state governments for Canadian prescription drugs cannot be met. CIPA Executive Director David MacKay said, “There isn’t a large enough supply to keep up with such a demand. Prescription-drug budgets for large states can easily run into hundreds of millions of dollars. We’re not designed to supplement state budgets” (Kuxhaus 2003).

The diversion of prescription drugs to the United States from Canada’s retail drug supply chain is increasingly a matter of concern for Canadian consumers. Patient groups, such as the Best Medicines Coalition, are concerned about drug shortages for Canadian patients as In-
ternet drug sellers divert products from pharmacy shelves to mail order distribution warehouses that serve the U.S. market (Higgins 2003). A pharmacy adjacent to the Winnipeg Health Sciences Center recently fell short of essential drugs used to treat brain cancer and leukemia, forcing the pharmacist there to appeal to the manufacturer for emergency supplies to meet the urgent needs of patients. These same drugs were, on the same day, available on the Web sites of several Manitoba-based Internet pharmacies to American patients who could pay a higher price.

A recent survey of Manitoba pharmacists reveals that “Not only are pharmacists having difficulty meeting their patients’ prescription needs, but they are also spending more time sourcing drugs and have less time to provide vital counseling to their patients.” According to the same survey, there is a growing shortage of pharmacists in Manitoba as more leave community practice for the more lucrative opportunity in mail order prescription drug exporting to the United States (Internet Pharmacy 2003).

Effect on medical professional standards of practice

Cross-border Internet pharmacies encourage less than ethical behavior from a number of vital participants in our health care system. For example, these individuals will seek out physicians who for a fee will cosign a prescription for a U.S. patient whom they have never seen. In addition, they entice pharmacies to order more products than they need and for a premium, then pass on the surplus to an Internet pharmacy, thereby acting as unlicensed wholesalers. This form of practice, which fosters the erosion of professional values with financial reward, merits close examination by Canadian legislators.

Professional organizations representing physicians and pharmacists across Canada and the United States overwhelmingly agree that mail order importation puts patients at risk. Representatives of the College of Physicians and Surgeons of Manitoba argue that “with no face-to-face contact between the cosigning physician and the U.S. patient, Internet drug delivery is breaching the College’s standards of practice.” The Nova Scotia College of Pharmacists issued a statement in 2002 that clearly sets out cross-border dispensing as a breach of practice. Furthermore, the New Brunswick College of Physicians and Surgeons suspended the license of a New Brunswick physician, also licensed in Maine, who was cosigning U.S. prescriptions for a Manitoba Internet pharmacy (Squire 2002).

Abuse of the personal-use exemption

Without action at the federal level, the unregulated import and export of prescription drugs will only expand. Abuse of the personal-use exemption, in the best-case scenario, allows Canadian commercial mail order drug sellers to provide lower-cost drugs by diverting prescription drugs from Canadian distribution channels. In the worst-case scenario, it provides an opportunity for unscrupulous commercial enterprises to evade regulated standards for drug approvals and distribution, resulting in the distribution of unapproved or substandard products to unknowing U.S. consumers.

References


The Verified Internet Pharmacy Practice Sites (VIPPS) program was launched in 1999 by the National Association of Boards of Pharmacy (NABP) to accredit legitimately operating online pharmacies in the United States that are prepared to practice pharmacy via the Internet. VIPPS-certified online pharmacies post the digital VIPPS Seal on their Web sites as a tool that consumers and businesses can use to identify reliable and trustworthy online pharmacies. Nearly 5 years ago, a task force convened to develop standards for the VIPPS program. Representatives from the U.S. Food and Drug Administration, boards of pharmacy, and consumer groups, among others, were present. Seventeen core criteria initially were approved and remain integral to the program today.

Among other things, VIPPS criteria require that the pharmacy maintain procedures to authenticate prescriptions, uphold the confidentiality of patient information, offer pharmacist consultation, handle reports of medication errors, and ship controlled substances. The program is neither regulated nor maintained by the pharmaceutical industry and is operated solely for the benefit of consumers, regulators, and the public. So far, 14 online entities have been awarded VIPPS accreditation (see Table).

After NABP receives an application for VIPPS accreditation, we contact our member boards of pharmacy and verify that all of the applicant’s pharmacy licenses are valid. Of note is the VIPPS criterion that requires pharmacies to refuse to dispense prescription medications that have been ordered based on online or telephonic medical consultations (NABP 2003). By reviewing the applicant’s Web site, and checking the names of the Web site and pharmacy against NABP’s clearinghouse of rogue site information, NABP ascertains whether the pharmacy is selling drugs based on online consultations and whether it has an international affiliation through which unapproved drugs may be illegally dispensed or shipped into the United States. NABP also reviews the applicant’s policies to ensure that they meet the VIPPS criteria.

The most important component of the VIPPS certification process is the onsite inspection. To verify that a pharmacy is not an illicit operation that is functioning out of someone’s garage or bedroom, NABP personnel review the pharmacy’s operations on site and interview staff in the areas of pharmacy practice, shipping, human resources, and information technology. Once NABP is satisfied that an online pharmacy’s operations and policies meet the intent of the VIPPS criteria, the entity is awarded VIPPS accreditation and a digital seal of approval for posting on its Web site.

After accreditation is awarded, annual reviews are conducted, along with random re-inspections. A certified online pharmacy can anticipate seeing a VIPPS team at least once every 3 years to ensure that it is continuing to operate in accordance with VIPPS standards.

The U.S. VIPPS program is complemented by a Canadian VIPPS program, which was launched in late 2003. Earlier that year, NABP signed an agreement with the National Association of Pharmacy Regulatory Authorities, NABP’s sister organization in Canada, to certify legitimately operating online pharmacies in Canada that are prepared to practice pharmacy via the Internet. It should be noted that any Canadian pharmacy that illegally ships prescription medica-

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SOURCE: NABP 2004
Pitfalls await customers of rogue pharmacies

Both the U.S. and Canadian VIPPS programs are important consumer safety initiatives because, increasingly, consumers have been turning to suspiciously and illegally operating online pharmacies to meet their prescription medication needs. While the consumers’ motivation often is to save money on prescription products — e.g., purchasing what is purportedly generic sildenafil citrate (Viagra) from an unknown provider for $2 per dose instead of paying $8 per dose for brand-name Viagra from legitimate U.S. sources — some seek to obtain drugs without having to first go through the process of obtaining a physical examination and a legitimate prescription, and others wish to easily obtain controlled substances to support their burgeoning drug habits.

Whatever their reason for visiting a rogue site, consumers often are left the poorer for the experience. Some become the victims of fraud. They submit their order, provide their credit card information, and never receive the product.

In fact, those consumers who reported to the NABP the amount of their monetary losses due to fraud have claimed damages totaling almost $12,000.

Although they may think otherwise, these defrauded customers are the fortunate ones, because they are spared the potential for injury from possible ingestion of counterfeit medications, such as tablets stamped “finastide [sic]” (finasteride [Propecia]) from the United Kingdom, compounded sildenafil from Asia, or sibutramine hydrochloride monohydrate (Meridia) tablets shipped loose in a plastic bag from Thailand.

Consumers who illegally import medications also could receive misbranded, defective, or potentially dangerous products. For example, Roaccutane is a version of isotretinoin (Accutane) that is unapproved for use in the United States. Roaccutane is not available through legitimate channels in the United States but is easily acquired online. A vitamin-A derivative, isotretinoin is used to treat severe acne and is a well-known teratogen that is capable of causing severe birth defects (Roche 2003). For that reason, a serum pregnancy test is required before this medication can be prescribed to a woman of childbearing age in the United States. Yet with a few keystrokes and clicks of the mouse, a woman can bypass this process, which may be perceived as nothing more than an annoyance, and buy the product without a prescription, let alone a pregnancy test, from a rogue international site.

Many Americans patronize international online pharmacies, particularly Canadian sites, and the list of complaints that NABP and our members have received about their experiences and purchases is long. In addition to dispensing medications without prescriptions, international online pharmacies may dispense incorrect or misbranded medication; advertise Canadian drugs but ship drugs from another country, such as an Asian nation; dispense products that are available over the counter but for which a prescription is required in the United States, such as acetaminophen with codeine (Tylelenol With Codeine), which is favored by substance abusers; and many sites do not review patients’ drug regimens for medication interactions, which has resulted in patients receiving duplicate therapy — either multiple medications in the same class or identical chemical entities that are marketed under two different brand names in the United States and the foreign country, respectively.

A frequent ploy used by Canadian and other international rogue sites is to suggest that U.S. federal law regarding the purchase of drugs from foreign sites is ambiguous. In fact, it is quite clear, stating that it is illegal to introduce unapproved drugs into U.S. commerce (Federal Food, Drug, and Cosmetic Act, §§ 331(a) and/or (d), 2003), that U.S.-made medications that are shipped outside the United States and later imported into the United States are unapproved (Federal Food, Drug, and Cosmetic Act, § 381(d)(1), 2003), that foreign versions of U.S.-approved drugs are deemed unapproved (Federal Food, Drug, and Cosmetic Act, §§ 331(a), 331(d), and 355(a), 2003), and that only a manufacturer may import drugs into the United States (Federal Food, Drug, and Cosmetic Act, § 381(d)(1), 2003).

Notwithstanding the complaints set forth above, NABP believes that consumers often are reluctant to report problems they encounter with Canadian Internet pharmacies. Such a complaint could be tantamount to an admission of improper importation of drugs, which consumers fear could lead to legal consequences, confiscation of the drugs, or both. These consumers also may be concerned about causing legal problems for the Canadian pharmacy, and they may worry about losing their source for less expensive medications if authorities shut down the online pharmacy or U.S. company that is facilitating drug importation from Canada.

Online filing of complaints

Since the inception of the VIPPS program, NABP has operated an e-mail reporting feature on our Web site that allows the public to notify us of suspiciously or illegally operating online pharmacies (NABP 1999). The complaint may be filed anonymously, if desired. To pursue a complaint, NABP needs to know the URL of the suspicious In-
ternet site. It is helpful if the consumer reports the date that the site was found, how the site was found, why the site seems suspicious, whether anyone was harmed by the actions of the site operators, the company’s location (if known), and whether the complainant wishes to be contacted for more information. NABP’s goal is to identify the location of the Web site and its affiliated pharmacy (or pharmacies), so that NABP can notify appropriate regulatory authorities.

VIPPS staff investigates every complaint received. An investigation often involves going through the ordering process, particularly to review graphics and the waiver of liability and patient-responsibility statements, which sometimes include clues regarding the Web site’s location. Staff hunts for any contact information posted on the site, as well as “WHOIS” Web site registration information that is available through numerous domain-name registration companies. Frequently, a site’s registration information is insufficient or unavailable, because some rogue online pharmacies hide behind companies that allow Web sites to be registered anonymously; the contact information that appears is that of the sheltering company from which the domain name was purchased.

Over the years, VIPPS staff has encountered many unique domain names or Web site addresses that actually are linked to or affiliated with a single “mother ship” company. The number of affiliated Web sites linked to the mother ship business could reach the hundreds, creating the impression that many more rogue online pharmacies exist than actually do.

NABP’s Web site also provides links to state boards of pharmacy and agencies for complainants who wish to provide information directly to a regulatory group. Alternatively, NABP can act as the conduit that forwards the complaint to the appropriate state and/or federal regulatory agency. If a complaint is not forwarded to a regulatory agency, it is almost always because staff cannot reasonably determine the U.S. state or the nation where the Web site or pharmacy is located.

**States’ actions against rogue online pharmacies**

Most states require nonresident or out-of-state pharmacies to hold a pharmacy license (e.g., Illinois Pharmacy Practice Act, § 85/16a, 2003). Five states, Georgia, Massachusetts, New Jersey, Pennsylvania, and Wisconsin, as well as the District of Columbia, do not require a nonresident pharmacy to hold an in-state license if it ships medications to residents of that particular jurisdiction. Nevertheless, the pharmacy laws of most states do not permit the licensing of international pharmacies within their jurisdiction. On the other hand, a few states’ laws could be interpreted to allow foreign pharmacies to become licensed. Because the more stringent federal law prohibits international pharmacies from shipping unapproved medications into the United States, however, these states would not license international pharmacies. Therefore, notwithstanding state laws, foreign pharmacies must overcome legal hurdles at the federal level before they can legitimately operate in the United States.

Some international pharmacy sites emulate the predominantly American habit of offering online medical consultations, which generate revenue in addition to that received for the drug being dispensed. Three states (California, Texas, and West Virginia) have laws specifically prohibiting the dispensation of prescription medications based on online consultations (e.g., Texas State Board of Pharmacy Rules, § 291.34, 2003). Pharmacists and pharmacies cannot dispense medications that have been prescribed on the basis of telephonic, electronic, or online consultations without the benefit of an in-person examination; neither can they dispense medications that have been prescribed as the result of an invalid relationship between a patient and a prescriber — if the pharmacist knows or reasonably should know about the improper consultation or invalid patient-prescriber relationship. Many other states use existing laws governing good faith and professional conduct to prosecute pharmacists and pharmacies that dispense prescriptions based on these types of cyber, or electronic, consultations.

In response to complaints about rogue Canadian online pharmacies and those businesses that assist consumers in unlawfully importing prescription medications, nearly two-thirds of the states have taken some type of action to combat this illegal cross-border trade. Facilitators are U.S. businesses that assist consumers in importing medications by allowing them to fax or call in a prescription to Canadian pharmacies with whom the facilitator or storefront has a relationship. Rx Depot may be the facilitator that has drawn the most attention in the United States. The state of Indiana is seeking an injunction against the firm, and Oklahoma was successful in obtaining a temporary restraining order against it (Oklahoma State Board of Pharmacy 2003). Arkansas has sent a warning letter to Rx Depot (Campbell 2003) and, importantly, a federal court recently issued a nationwide injunction against the operations of Rx Depot, stating Rx Depot violated the law and that the safety, purity, and efficacy of drug products obtained through Rx Depot cannot be assured (Eagan 2003).

States also have sent warning letters to Canadian pharmacies. Wyoming, for example, has sent a cease-and-desist letter to ThriftyMedsNow Pharmacy in Manitoba (Corder 2003), and Canada Direct Pharmacy in British Columbia received a cease-and-desist letter from North Dakota (Anderson 2003).

**Conclusion**

As regulators try to combat the proliferation of rogue Internet pharmacies that export unapproved medica-
tions to the U.S. and online pharmacies that allow consumers to purchase prescription drugs without first having to obtain a valid prescription, the numerous benefits of the VIPPS program increasingly become evident. VIPPS accreditation provides regulators with an additional safety net, because the program comprehensively reviews the operations of in-state and out-of-state pharmacies that may dispense medications to residents within their state. This additional layer of oversight is especially important at a time when state and federal regulatory agencies suffer from an increasing lack of resources, staff, and funding. VIPPS certification is an excellent due diligence tool for businesses to utilize if they are considering entering into a financial relationship or joint venture with an online pharmacy. And, finally, consumers can utilize the VIPPS Seal to identify accredited online pharmacies that practice professionally and in compliance with state and federal laws.

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Texas State Board of Pharmacy Rules. Title 22, Texas Administrative Code, § 291.34, 2003.
For decades, if not centuries, pharmaceutical products have been imported at great risk into the United States from other countries. Reimportation of pharmaceutical products carries similar but somewhat lesser risks and occurs when U.S.-manufactured drugs are exported to another country and then brought back to the United States.

Historically, unregulated imported drugs have entered the United States through individuals who inhabited the areas bordering Canada and Mexico. Another major contributor to illegal importation of pharmaceuticals was the return of international travelers to this country with medications that they had obtained abroad. Currently, the rate at which pharmaceuticals are being imported into this country is at its highest to date (Flaherty 2003). Moreover, the demand for imported drug products has grown dramatically and has spread throughout the United States.

From the 1960s through the 1980s, the U.S. drug-distribution system was considered by many to be the safest in the world. Drug products had to be approved by the U.S. Food and Drug Administration, making it a “closed system,” and the commercial and personal importation of pharmaceuticals was strictly controlled. During that period, the government did not permit the importation of prescription drugs, except for limited commercial importation by the product manufacturer.

Today, gaping holes exist in the protective barrier of the U.S. drug-distribution system. These holes have facilitated prescription drug diversion, which is the illegal removal or the reintroduction of a pharmaceutical product from an authorized drug distributor. As an example, consider a drug manufacturer that sells a product to a foreign country at a discounted price only to find it illegally returned (diverted) to the domestic market.

Additionally, manufacturers may sell a product to a nursing home or hospital at a reduced price, only to find it being illegally diverted to the retail drugstore market. In another example, a patient may illegally sell medications back to the pharmacy or to another agent who diverts the product back to an authorized or unauthorized distributor. Frequently, when consumers do this, health insurance, Medicaid, or another payer paid for the product. Drug diversion can occur on a small scale, as well, such as with the sharing of prescription medications, or it can be very complex. Drug diversion may involve authorized agents and rogue distributors, millions of dollars, different countries, organized crime elements, and multitiered distribution networks.

The combination of market elements that give rise to the distribution of diverted and, often, counterfeit drugs is commonly referred to as the “gray market.” This gray market comprises secondary drug wholesalers who are involved in illegal drug importation, as well as the introduction of counterfeit medications, labels, and packaging.

Laxity has fostered the growth of a host of fraudulent health care operations, distribution operations, and middlemen operating pharmaceutical warehouses. Moreover, peddlers have set up rogue Web sites from which to sell prescription drugs that include narcotics, psychotropic drugs, anabolic steroids, diet pills, and drugs to enhance sexual performance.

The vast majority of pharmaceuticals imported into the United States are not FDA approved. Many are of poor quality or are counterfeit and have found their way into American homes and the U.S. drug-distribution system (FDA 2003a, Gaul 2003a). As depicted in Figure 1, prescription drug diversion, drug counterfeiting, and drug importation are strongly related. Each can stand alone, but they often feed off each other.

**FIGURE 1** Linkage between drug diversion, drug counterfeiting, and drug importation
Drug importation and the law

Bringing unapproved drugs into the United States via mail or personally carrying products into this country is illegal (Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 33). The FDA prohibits the interstate shipment of unapproved drugs. Unapproved drugs consist of any drug, including foreign versions of U.S.-approved drugs that have not been manufactured in accordance with and pursuant to FDA approval. The only entity that can legally import pharmaceuticals is the manufacturer. The FDA does recognize, however, that importation of an unapproved drug is necessary in certain situations, and thus has outlined the following variance of the law:

- When the intended use is unapproved and for a serious condition for which effective treatment is not available in the United States
- The drug product is for personal use only
- There is no commercialization or promotion to persons residing in the United States by those distributing the drug product
- The product does not represent an unreasonable risk

The FDA emphasizes that this variance does not translate to the license to import unapproved, and therefore illegal, drugs into the United States. The FDA states that this guidance is not intended to cover foreign-made versions of drugs that already are available in the United States.

The question then arises: Why are so many imported drugs coming into the United States? The candid answer is that this is a political issue. The FDA and U.S. Customs have not enforced the law in an attempt to avert arresting the average American citizen. The FDA has prosecuted the organizations that facilitate illegal drug importation, however.

Cause of the problem

Widespread drug importation can be traced to the high utilization and cost of pharmaceuticals in the United States and to the associated lure of cheap pharmaceuticals. Pharmacies in some foreign countries have much lower government-controlled drug prices. Also, in countries where the economy and standard of living are relatively weak, drug prices are lower and drug regulations are lax, thus facilitating the production of less costly pharmaceuticals. An abundance of worldwide suppliers of less costly pharmaceuticals are therefore available to Americans.

Although many Americans travel outside their country’s borders to obtain prescription drugs, most people order pharmaceuticals via the World Wide Web and a credit card. Thousands of pharmacy Web sites exist, only some of which represent legitimate pharmacies. The development of the Internet, coupled with the American demand for cheaper pharmaceuticals, thus facilitated widespread prescription drug shopping and importation.

Another source of drug products is a new business that has emerged — the pharmacy storefront — with operations that have spread across the United States. These are not truly pharmacies; they neither stock nor sell drug products, and they do not employ pharmacists. For a fee, these operations will fax your U.S. prescription to a foreign pharmacy supplier (primarily located in Canada), where the prescription is filled and the drug is then mailed directly to your home.

These operations have been under increasing scrutiny from the FDA and the federal judicial system. In the fall of 2003, a federal judge shut down 85 RxDepot stores for facilitating drug importation (CNN 2003). Still, many of these businesses continue to operate.

Associated problems

Given the many fraudulent Internet pharmacy providers, it is extremely difficult for consumers to distinguish them from legitimate Internet pharmacy providers that are licensed and conduct business following strict local, state, and federal regulations and that have strong internal standards.

To address this situation, the National Association of Boards of Pharmacy has developed a quality inspection process for Internet pharmacy operations. If a pharmacy meets their standards, it is designated as a Verified Internet Pharmacy Practice Site (VIPPS). The VIPPS designation appears in a highly visible position on the front page of the site, so that consumers may identify the approved sites readily.

Investigators have found that many of the rogue pharmacy sites on the Internet are operated by felons — criminals with links to organized crime, drug cartels, and terrorist organizations (Global Options 2003, Gaul 2003b). Many of these rogue sites appear one night and disappear the next day. Often, it is difficult to track the physical location of the pharmacy and the Web site, as registration information may be false. Also, the Web site address may be deceptive; for example, some operators have used the word “Canada” in their Web site title, when in fact the site is not located in Canada (Global Options 2003). Thus, consumers must be made aware of the existing potential for deception and fraud.

Many times, consumers do not need a prescription to obtain one of these pharmaceutical products via the Internet. Moreover, buyers may not even know the origin of the pharmaceutical product, nor do they receive any product quality assurance with respect to their purchase. The FDA has determined that most of the drugs coming from foreign Internet pharmacies have not been approved, and thus they may be counterfeit or substandard products.
About imported pharmaceuticals

In the summer of 2003, the FDA examined a sample of 1,153 imported pharmaceutical products that had arrived in four U.S. international mail facilities (New York, Miami, San Francisco, and Carson, Calif.). A total of 1,019 (88 percent) of the pharmaceutical products examined were not FDA approved; the products originated from varying countries. The FDA summarized the problems with the drugs (FDA 2003a):

- Not FDA approved
- Contained too little, too much, or no active ingredients
- Expired or had a false expiration date
- Contaminated
- Stored at the wrong temperature or under unsafe conditions
- Counterfeit
- Fraudulently or inadequately labeled, had no labels, or labels were written in a foreign language
- Withdrawn from the U.S. market
- Intended for use in animals and not approved for usage in humans
- Inappropriately packaged
- Illegal narcotics

FDA Commissioner Mark McClellan, MD, PhD stated: “There is no evidence that unapproved drugs are becoming any safer or more reliable. Given the FDA’s limited resources and authorities to detect and block potentially unsafe imports, we are concerned about any measure that would increase the flow of these unapproved drugs or provide easier channels for them to enter the United States” (FDA 2003a).

Extent of the problem

At a congressional hearing in June 2003, Pennsylvania Rep. James C. Greenwood reported that 150,000 packages containing drug products arrive weekly at the Miami international mail facility. Greenwood estimated that if the Miami facility is representative of the others, a total of approximately 20 million packages of drugs are delivered each year to the 12 international mail facilities in the United States. This estimate does not include United Parcel Service, Federal Express, or other private delivery services. From 2001 through 2003, the increase in imported pharmaceuticals has been 1,000 percent.

Moreover, many of these mail packages contained more than one drug product; some had quantities far in excess of the allowable 90-day supply. Based on these results, one can begin to grasp the difficulties that the Customs and FDA officials must face in attempting to ensure safety and quality relative to imported drugs.

Counterfeit medications

The World Health Organization defines a counterfeit medication as one that “…is deliberately and fraudulently mislabeled with respect to identity and or source. It can apply to both branded and generic products, and counterfeit products may include products with the correct ingredients, or wrong ingredients, without active ingredients, with insufficient ingredients, or with false labeling” (WHO 1999).

Counterfeit medications are a widely documented global problem. Although extremely difficult to measure, the estimates of counterfeit drugs run from 2 to 8 percent of the world’s pharmaceutical market. Counterfeit drug production is estimated to be a $31 billion market (WHO 2003). Nevertheless, there is agreement that the prevalence of counterfeit drugs is most likely underestimated (Kapp 2002).

There are wide differences from country to country relative to the extent to which counterfeit drugs are a problem. For example, such drugs comprise 30 to 50 percent of the market in many South American, African, and Southeast Asian countries. The leading sources of counterfeit drugs are China, India, Russia, Brazil, Pakistan, Mexico, many Southeast Asian countries, and many of the Middle Eastern countries. The number of counterfeit medications will continue to remain a threat to the United States, due to the high-dollar market potential that they carry. Between 1996 and 2000, the FDA investigated four to six counterfeit cases annually. In 2001, there were 20 cases; in 2002 there were 22; and through October 2003, the FDA has had 22 cases (Kontnik 2003).

Drug counterfeiters generally are run as small operations. Often, the counterfeiters are legitimate manufacturers during the day, but at night they formulate counterfeit drugs. Many have been linked to organized crime, the international narcotics trade, and terrorist organizations. Corruption is widespread among drug counterfeiters; attempts at bribery and threats to politicians and government officials are standard practices. The tactics applied in these operations include mixing counterfeit drugs with legitimate products, changing labels, and paying off distributors to introduce counterfeit products. They generally segment their various manufacturing and distribution functions, so that each component is unaware of the other. In fact, counterfeit drug operations tend to involve many different countries; raw materials come from one country, ingredient formulations may come from another, the final dosage form may be produced in a fourth country, and containers, yet another country. Drug packaged in a sixth country then may be shipped to multiple countries before arriving at a final destination (Rush 2002).
Arbitrage — drug diversion, counterfeiting, and importation

It is the arbitrage — the variations in price for the same products, based on geographic areas or market segments — that drives drug diversion and fuels corruption and counterfeiting. The price difference between countries often stimulates a product’s diversion to another country. When this occurs, someone within the country that is importing the drug — either legitimately or fraudulently — negotiates and purchases the cheaper product. All or a portion of the product is then diverted and sold to a higher-priced country or market area.

Due to this diversion, the supplies to the importing country will be cut; the diverter then must establish a way to supplement their drug supplies to meet the country’s needs. The cheapest and easiest way for the diverter to supplement this supply is to mix in a counterfeit product. This buying and diverting process can occur multiple times within a country as the product flows through the drug-distribution chain. Each time this occurs, a diverter makes a profit, and each time this occurs, more counterfeit drugs enter the system. Thus, the original product may be cut multiple times with counterfeit products. In the end, counterfeit drugs may have entered many countries through the gray market. This includes the United States via rogue Internet operations or through the U.S. gray market via secondary wholesalers.

Figure 2 is a representation of this diversion process. An example of this international diversion scheme occurred in 2002, when 20 percent of the AIDS medications manufactured by GlaxoSmithKline in the United States and destined for Senegal, Ivory Coast, Congo Republic, Togo, and Guinea were diverted to Western Europe (Reconnaissance 2002).

Within the United States, prescription drug diversion also occurs due to arbitrage; in this case, however, price differences are either between classes of trade for pharmaceuticals (i.e., hospital vs. retail market) or due to price breaks or discounts offered to drug distributors or wholesalers by manufacturers and other wholesalers. The United States has three main wholesalers that handle more than 90 percent of pharmaceutical products that are distributed via wholesalers. Drug wholesalers distribute approximately 54 percent of all prescription drugs; the remaining products are sold directly from the manufacturer to the hospital or retail outlet. In addition, there are approximately 12 to 15 regional wholesalers, plus there are literally thousands of what are referred to as “secondary” wholesalers. These secondary wholesalers are small firms and represent the weak link in the system (Kontnik 2003). Some have been tied to prescription-drug diversion schemes, and the importation of counterfeit drugs (FDA 2003b). Overall, this segment of the industry, including drug wholesalers and drug repackaging companies, is loosely regulated. With more counterfeit products entering the system, however, some states are tightening the regulatory requirements for wholesale drug distributors (Rhein 2003).
Vulnerable points

Figure 3 is a schematic flow chart depicting the drug-manufacturing process and the drug-distribution system. The chart highlights some of the vulnerable points, showing where drug diversion, fraud, and other criminal behaviors — including the introduction of a counterfeit product — may occur. It can be seen that acquiring a drug product's active ingredients or chemical components represents the first vulnerability point, followed by the manufacturing process. After the product has been manufactured, the second and probably the weakest point is the distribution of the product. As listed, many deceptive, fraudulent, and criminal behaviors can occur during the drug-distribution phase, including product theft, drug diversion, relabeling and repackaging (e.g., changing expiration dates and/or drug strengths), and the introduction of substandard/counterfeit products. Employee theft, fraud, and drug diversion also can occur at the drug's supposed final outlet site.

Lastly, the consumer has been implicated in fraud and drug-diversion schemes. Most recently, it was reported that Medicaid patients have been obtaining prescription drugs fraudulently and selling the drugs to the gray market via drug diverters/buyers, who in turn sell the products to secondary wholesalers, drug peddlers, or distributors who act as middlemen.

Drug-storage reclamation centers represent another vulnerable point, one that is not depicted in the flow chart. Such sites exist at hospitals, long-term care institutions, and other health care institutions where drug products are used. These reclamation sites are for drug products that have been discontinued, instances in which the patient has died or has been transferred to another facility, or when the life of the product has gone beyond the expiration date. These drugs are stored for a short time at these locations and then either destroyed or shipped back to the manufacturer, wholesaler, or another location for disposal. Products at these sites are extremely attractive to drug diverters and thieves, who repack or relabel these drug products and then divert them to the gray market.

Conclusion

The flow of imported pharmaceuticals has caused many concerns and problems for our society; local, state, and federal government agencies; patients; health care practitioners; law enforcement agencies; and regulators. Our federal, state, and local government authorities are facing a quagmire of issues with the escalating number of imported prescription pharmaceutical products, which include habit-forming narcotics. Those politicians who are advocates of drug importation are now hiding behind the veil of the elderly. Congress has been in touch with the anger of American seniors with respect to drug prices. In an effort to get cheaper drugs to the elderly through importation, however, they have put all Americans and our drug-distribution system in jeopardy.

Heightened availability of Internet pharmacies and the growing American appetite for cheaper pharmaceuticals are increasing the risks faced by the American public with respect to fraudulent activity in this area. Undoubtedly, increases in inappropriate access to prescription drugs will result in higher health care costs if we cannot gain control of the situation. Without effective steps to improve this situation, there will be a continued increase in fraud, corruption, and drug counterfeiting. Such a scenario would result in more deaths and disabilities, and continued destabilization of our safe drug-distribution system.

References


A closed system with a strong federal and state regulatory infrastructure, the U.S. drug supply has been held up as the gold standard for the safety of pharmaceuticals. This infrastructure has developed over the last 65 years, drawing on knowledge and experience gained from the Food, Drug, and Cosmetic Act that passed in 1938. In that time, the American people have come to expect a high level of safety and security in the drug supply.

This level of safety is assured if a drug is purchased at a licensed pharmacy in the United States, which is part of this closed system that provides critical safety assurances at every point in manufacturing, distribution, prescribing, and via patient education.

Buyer beware
A drug that is purchased outside the United States does not come with the assurance of safety and quality, however; in fact, it becomes a buyer-beware situation, because, to gain a profit, unscrupulous people dispense drugs that are expired or mislabeled. Unfortunately, the FDA has neither the resources nor the legal authority to protect Americans from drugs that are imported into this country.

In U.S. mail distribution centers, sheer volume prohibits the monitoring of all suspect packages by FDA inspectors. In the summer of 2003, over a 3-day period, the FDA and the U.S. Customs and Border Protection conducted a series of spot examinations of imported mail shipments. Approximately 100 parcels were selected daily, and more than 1,100 imported drugs were examined. Of those, 88 percent were revealed to be unapproved drugs (FDA News 2003), many of which are associated with significant adverse events when used improperly. Instructions, packaging, and labeling tended to be inadequate, and often, the tablets were crushed and broken. Drugs that had been removed from the U.S. market 25 years ago were among the contents, as were veterinary drugs that had been banned for use in humans. Also found were drugs with dangerous interactions and drugs that necessitate monitoring the patient’s liver function. Additionally, many controlled substances were found, such as diazepam, codeine, and anabolic steroids.

Of these illegally imported drugs, 16 percent originated from Canada, 14 percent from India, 14 percent from Thailand, a significant amount from the Philippines, and the remainder was from a host of other countries.

One consumer shared with the FDA that he had purchased gabapentin, an anticonvulsant, via the Web. The tablets were dispensed in a dangerously large volume, constituting the equivalent of at least a year’s supply, with more than 1,200 tablets in the package, and the drug expired within a month of the date that was stamped on the package.

Such examples are representative of problems associated with imported drugs and those ordered via the Internet from around the world. The FDA is seeking to maintain the integrity of our nation’s drug supply despite the threat that is presented by counterfeit drugs. In the United States, counterfeit drugs are still rare. With the increasing occurrence at the global level, however, it has become essential to ensure that systems are in place so that this high rate does not extend to the United States. Even one incidence of a counterfeit drug could have severe public health implications.

A brief history
In the 1980s through the early ’90s, counterfeiting of bulk active pharmaceutical ingredients was the most common problem, mostly comprising drugs imported from China. From the mid-’90s to the present, counterfeiters have focused on finished dosage forms, because of the potential for greater profit.

Figure 1 shows how dramatically the number of cases of drug counterfeiting has risen in the last 6 years. Counterfeiters are becoming increasingly sophisticated and organized. The current rate could continue to climb, but the FDA is putting measures in place to assist in containing this problem.

Counterfeiters often use sophisticated and meticulous processes to copy an authentic drug as well as its packaging and labeling (Figure 2). In many cases, it is only with the use of elaborate forensic techniques that differences between authentic and counterfeit drugs can be detected.

Public health concerns
The primary public health concerns resulting from counterfeit drugs are potential side effects and therapeutic failures. In the case of cholesterol reduction, for example, a physician who is treating a patient whose
Lipid levels are not improving may not realize that a patient is ingesting a counterfeit drug and therefore would be likely to attribute the poor response to another cause.

In July 2003, FDA Commissioner Mark McClellan, MD, PhD convened a task force to evaluate the growing counterfeit drug problem in this country and to develop a strategic plan to combat counterfeit drugs. The charge to the task force was to consider ways to prevent the introduction of counterfeit drugs, help minimize the risk of consumer exposure to such drugs, facilitate their identification, and avoid adding unnecessary costs to the drug-distribution system.

The commissioner called for an interim report within 60 days of the task force’s establishment, and a final plan within 6 months.

**FDA interim report**

In October 2003, the FDA’s interim report was issued, outlining potential options for public comment. The report integrates many new and emerging technologies that offer promising ways to assist in preventing and containing the problem of counterfeit drugs. Fortunately, in the next few years, more of these measures will be more fully developed, implemented, and tested.

The report includes an overview of the distribution system and the vulnerabilities in the system as drugs pass from manufacturer to patient. The report also includes a discussion of the Pharmacy Model Practice Act that is in place for the licensing of wholesale distributors, as well as an outline of the inadequacies with respect to the penalties for counterfeiting.

Track-and-trace technologies. A substantive discussion on anticounterfeiting technologies highlights the importance of track-and-trace technologies for products in the distribution system.

Radio frequency identification (RFID) is one such methodology, and uses a tiny information chip on the product package that identifies the product and allows it to be tracked and traced. Electronic readers — located at strategic points as the product travels from the manufacturer, wholesaler, and retailer — transmit information on the product’s precise location to a database that tracks who handled the product while it was en route to the pharmacy. These chips will become increasingly sophisticated in the future, possibly being able to provide readings on temperature and the conditions under which a product was stored.

Bar codes provide another effective method for tracking drugs.

Despite the expense associated with the implementation of these technologies, money actually is being saved...
due to the resulting increased efficiency relative to inventory control and antitheft management, as well as the anticounterfeiting benefit.

Authentication. The other promising area of technology is authentication. Overt and covert technologies can be used for authentication. Overt technologies are those that are known and identifiable by all users. These overt markers enable people along the distribution chain simply to look at a product or its label to determine its authenticity.

Covert technologies are known and detectable only by a small number of people. These include inks or dyes that will fluoresce within a specific ultraviolet range, as well as invisible bar codes and covert watermarks.

Forensic characteristics include chemical markers that are placed in the product, such as taggants, which do not affect the safety or efficacy but allow the manufacturer or an FDA laboratory to determine whether a product is authentic or fraudulent. Given that counterfeiters are becoming increasingly sophisticated, the challenges of identifying genuine products are growing, and so too must the sophistication and sensitivity of the technologies used to detect these fraudulent products increase as well.

The potential options described in the interim report for use in anticounterfeiting also include unit-of-use packaging, such as blister packs, which may reduce the likelihood of tampering. Currently, there is no federal requirement for prescription drugs with respect to tamper-evident packaging.

The FDA interim report asks for public comment on whether anticounterfeiting measures on packages and labels should target products at high risk for counterfeiting and for which counterfeiting poses serious health risks. The report also seeks public comment on the creation of a database of authentic pharmaceuticals to be used by the FDA and/or pharmacists and retailers when a product is suspect.

The National Association of Boards of Pharmacy (NABP) is moving toward strengthening the Model Rules of Licensure of Wholesale Distributors, and has convened a task force for this express purpose. These model rules could then be adopted by states, through regulation or legislation. The FDA is working closely with the NABP in this effort to update the rules that were originally written in 1988.

The FDA also is working with wholesalers and pharmacy groups to develop a set of best practices to help ensure product security, and it will work with manufacturers as well. Additionally, the interim report seeks public comment on whether companies in the distribution chain should identify a specific individual or establish a security team to oversee this area.

In the interim report, the FDA recognizes that an efficient system does not yet exist to alert consumers and pharmacists about a specific counterfeit event or how to report a suspect counterfeit product. Manufacturers are not legally required to file a report with the FDA, because the counterfeit product in question did not come from the manufacturer who may be reporting it. Nonetheless, a voluntary system is in place, whereby the manufacturer notifies the FDA within 5 days of becoming aware of the counterfeit product.

Consumers and pharmacists also may find that they have suspect counterfeit drugs on their hands, without knowing how to report the incident. The agency is determining if MedWatch, FDA’s reporting system for adverse events and product problems related to pharmaceutical products, can be modified for use as such a reporting tool. The FDA also is establishing a counterfeit-alert network, in partnership with pharmacists and other health care professionals, along with consumer groups, which can be called on to disseminate the message quickly to all concerned parties if there is a counterfeit event.

Internally, the FDA is making changes to strengthen and improve its procedures and processes to ensure that in an event of counterfeiting, the FDA can respond expeditiously.

Increased consumer education and public awareness are essential, and the FDA is increasing its efforts in this regard, through its work with pharmaceutical manufacturers and wholesalers, as well as pharmacy and consumer groups, to develop effective, customized messages and strategies.

The FDA also will issue educational messages to consumers that offer instruction in protection from the threat of counterfeit drugs. Similar messages geared to pharmacists are being generated to alert them about important clues that help with the detection of suspect drugs — for example, a broken tablet or chipped tablet coating, unusual packaging, or a patient’s claim relative to a change in the taste of a drug. One counterfeit product came to the FDA’s attention because of reports of burning at the injection site. Also, a drug that is offered at an extremely low price sends out a red flag for counterfeiting.

The FDA is compiling and disseminating these important messages, and will continue to do so in an effort to educate both the public and private sectors.

To address this global problem, the FDA will align with international organizations in this effort. The FDA’s work with the World Health Organization is intended to increase communication, cooperation, and collaboration on a global level for antiterror operations. There are highly skilled criminal investigators working within the FDA, as well — many of whom work with Interpol and other international criminal enforcement groups, on a case-by-case basis. Such partnerships foster the development of more systematic approaches to reduce and eliminate the occurrence of counterfeiting.
In October 2003, the FDA hosted a public meeting with more than 70 speakers, each of whom provided views on the potential options presented in the FDA’s interim report to address the counterfeiting problem. There also was an opportunity for the FDA to explore and evaluate the available anticounterfeiting technologies at a technology forum that was held concurrently with the public meeting.

The FDA is continuing to meet with stakeholders, consumers, wholesalers, manufacturers, pharmacists, and other health care providers. As it is pressing forward on this learning curve, which is growing exponentially, the FDA has issued a strategic action plan and final report on counterfeit drugs.1

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1 On Feb. 18, 2004, the FDA released its Counterfeit Drug Final Report, which builds on the Interim Report discussed in within this article and is available at: «www.fda.gov/oc/initiatives/counterfeit/».

References


On Feb. 18, 2004, the FDA released its Counterfeit Drug Final Report, which builds on the Interim Report discussed in within this article and is available at: «www.fda.gov/oc/initiatives/counterfeit/».
Illegal importation of drugs is a topic of special importance that warrants both attention and action. While the long failure in the United States to provide a prescription drug benefit under Medicare contributed to the traffic of prescription medications across our borders, the problem will persist as more and more Americans price shop for drugs online.

Illegal importation poses a significant threat to public health and the nation’s drug supply, in no small part because the drugs coming into the country evade the safeguards and protections that the U.S. Food and Drug Administration provides.

Patients who purchase drugs from other countries do so at great risk — indeed, many are not under the care of either a physician or a pharmacist to help ensure that medications are taken safely and effectively.

In the United States, illegal importation has gained a foothold, because, too often, those who can least afford medication are paying the highest prices (i.e., those people who are without prescription coverage, including the unemployed and retired).

Annual health care spending continues to skyrocket — up 9.3 percent in 2002 to a total of $1.6 trillion, or about 15 percent of the nation’s gross domestic product (CMS 2002). Of that, prescription drugs accounted for $1.62 billion, or only about 10 percent of the nation’s health care expenditures. Why, then, do the media focus so much attention on this issue that involves only a small percentage of health care expenditures?

The answer is that the rate is steadily increasing. Only a few years ago, prescriptions accounted for just 8 percent of U.S. health expenditures. Analysts estimate that this figure will climb to 12 percent by 2010. Among all the expenditures for health care, costs for prescription drugs are rising at the fastest pace.

It should not be surprising, therefore, that consumers of drugs are looking for lower-cost alternatives. Cost rather than safety becomes their primary concern — a dangerous situation that could threaten public health.

That’s why it is increasingly important that we in community pharmacy emphasize the value of prescription medications over the cost, both in our communications with public policymakers and in our interactions with patients.

According to the World Health Organization, 50 percent of people who take medication do not take it properly. Furthermore, based on data from the Medical Expenditure Panel Survey, 13 percent of new prescriptions do not get filled (CFACT 2003). Moreover, this applies not only to patients with minor ailments, but also to those with more serious illnesses, including diabetes, asthma, and heart disease. Often, individuals who fail to take their medication properly ultimately require emergency room care, which is much more costly than the prescribed medication.

The fact is that prescription medications — taken properly and under the supervision of a health practitioner — actually reduce overall health expenditures. According to one study, for every $1 increase in pharmaceutical expenditures, there is a corresponding $2.11 decrease in medical costs (Lichtenberg 1996). In other words, it typically costs far less to treat illness and control chronic conditions through pharmacotherapy than other medical treatments, and patients who closely adhere to their drug regimens are much more likely to stay productive and avoid unnecessary hospitalizations and physician visits.

Other studies demonstrate that we as a nation spend more to address the consequences when patients do not take their prescriptions properly than we spend on the medications themselves. According to one estimate, for every $1 we spend purchasing medication, we spend $2 fixing a problem caused by improperly taken medication.

Therefore, the true value of drug therapy depends on the safe and effective use of medications. Prescription medications only work when taken properly, and pharmacists play a crucial role in helping to monitor drug compliance and guard against adverse drug reactions and interactions.

Today, we in community pharmacy face many challenges brought about by high drug prices. In terms of drug pricing, it is important to understand the role of community pharmacies, which provide not only the medications themselves, but health monitoring and other services that help ensure that drugs are used safely and effectively. Further, it is not only U.S. consumers who pay high prices for prescription drugs; pharmacies do as well. In fact, U.S. pharmacies pay more to purchase the
Another concern is the growing use of mandatory mail order prescription plans. As more and more government and private health plans require patients to use mail order pharmacies, the consequences can be the same as with illegal drug importation. Simply put, when patients receive medications in the mail, they may not be getting the important health services that community pharmacists provide.

While the National Association of Chain Drug Stores is not opposed to patients purchasing their medications through mail order, the choice should be a joint decision between a patient and physician so that the physician can ensure that patients comply with their drug therapies. Patients should not be forced to use mail order or be financially penalized if they do not, as our survey data show that most patients want the option to fill prescriptions at neighborhood pharmacies.

We continue, however, to oppose any public policy that encourages the illegal importation of medications. Simply put, medications are not just another commodity. The search for the least expensive drug has serious consequences for retail pharmacy and our society in general. Too often, patients are denied the pharmacy care that could improve health outcomes and save money in the long run. Our greatest fear is that in the quest for bargain medications, we may actually be jeopardizing public health. And that’s not good medicine.

Reference


Lichtenberg FR. Do (more and better) drugs keep people out of hospitals? Amer Econ Rev. 1996 May;86(2):384–388.
The issue of reimportation and importation of pharmaceuticals into the state of Michigan is just one of many challenges that Michigan pharmacists have been confronting for years.

In addition to reimportation, issues that Michigan’s pharmacists face daily include the battle over Medicaid reimbursement for pharmacy services, an ever-growing erosion of pharmacy services — from community-based prescriptions to out-of-state mail order dispensing, and frequent decreases in pharmacy dispensing fees for third-party prescription insurance programs. Furthermore, the increasingly strong desire of health care payers (and the general public) to obtain less expensive drugs presents a particularly difficult challenge. Pharmacists also must contend with a lack of recognition for the value they bring to the health care team, an oversight that contributes to patient indifference about the pharmacist-patient relationship.

With the rapid rise in drug costs, there has been an accompanying shift in consumer focus, away from the value of pharmacy services such as ensuring that patients receive the correct medications with the appropriate instructions and that they use them properly.

Proximity facilitates reimportation

The proximity of Michigan to a foreign country is unique. It is the only state through which citizens are able to leave the United States by traveling south to enter Canada. Michigan has four legal access points to Canada, which consist of a bridge and a tunnel in Detroit, a bridge in Port Huron, and a bridge in Sault Sainte Marie. Of the state’s 10 million inhabitants, more than half are no more than a 2-hour drive from Canada.

Most people in Michigan perceive Canada as the 51st state, because it is an English-speaking country and, for many Michigan residents, the ride is quicker than driving to another state. Controlling travel between the two nations is further complicated by the fact that more than 1,500 miles of Michigan’s shoreline along the Great Lakes border Canadian land.

Michigan residents have been crossing the border for years to get their medications, for two primary reasons: 1) the ability to purchase drugs over the counter versus through a prescription that is required in the United States, and 2) to take advantage of the enhanced value of the U.S. dollar over the Canadian dollar.

Political pressures have fueled consumers’ drive to purchase lower cost drugs in Canada. The cost of prescription drugs was a major issue in the 2002 U.S. Senate race in Michigan between Debbie Stabenow and Spencer Abraham. Sen. Stabenow continues to refer to this issue, expressing support for reimportation as she conducts activities in the state (Stabenow 2003). There are politicians at the local, state, and federal levels in Michigan, including Gov. Jennifer Granholm, who continue to view Canada as a source for lower-cost drugs. Many of these politicians schedule frequent bus trips for seniors and others from Michigan to Windsor, Ontario, to make such purchases. They calculate their savings and share that information with the press to further promote leaving the country to obtain medications. The politicians thereby promote the cost differences and add fuel to the fire.

Unlicensed storefront operations

As awareness of the price differences between the United States and Canada increases along with drug costs, patients without prescription drug coverage will continue to seek lower-cost options, as will companies who pay for their employees’ prescriptions. Cities across the state are helping to build awareness of storefront operations that provide pharmacy services in unlicensed venues by unlicensed individuals that engage in practices such as faxing prescriptions to mail order pharmacies in Canada. While storefront operations have proliferated in Florida in recent years, the expansion into Michigan is a phenomenon that has begun to occur in recent months.

To curtail these operations, the Michigan Pharmacists Association has filed formal complaints with the Michigan Consumer and Industry Services Bureau of Health, the state department that enforces the laws and regulations of the Board of Pharmacy. These complaints indicate that such storefront operations are in violation of the state public health code. In response, the bureau found no violation of state law but recognized the violation of federal law. Thus, the bureau referred the issue to the Michigan attorney general, who has not yet responded.

Safety issues nationwide

Bringing unregulated medications into the United States introduces serious issues pertaining to safety and quality. The U.S. Food and Drug Administration is not able to guarantee that such drugs are FDA approved nor...
that they are correctly labeled. The FDA continues to warn patients about the high percentage of counterfeit medications worldwide. Many patients assume that such medications are produced in the United States and shipped to Canada, but FDA inspections indicate that this is not always the case.

The issue of reimportation of drugs from Canada into the United States is extremely confusing to average consumers. The general perception is that drug manufacturers are overcharging patients for medications that they need for survival, and that they are profiting greatly by taking advantage of this need. Moreover, although consumers have heard that Congress passed legislation to allow drug importation from Canada, they are unaware that the law has not been implemented because the FDA cannot guarantee the safety of the drugs.

The dissolving pharmacist-patient relationship

The severing of the pharmacist-patient relationship is a serious problem that is associated with reimportation of medications and mail order purchases. This relationship is established through pharmacists’ face-to-face interactions with patients, which allows them to come to know and anticipate the patients’ specific problems and pharmacy needs. Yet this beneficial scenario is becoming more rare with the increased mail order purchasing and reimportation of medications.

Severing the direct relationship between the pharmacist and patient also raises medication safety concerns. When patients obtain medications by mail, they lose the advantage of having one database that has all their medications on file. In turn, the pharmacist who is dispensing the prescription loses the ability to review all the patient’s medications to identify possible drug duplications, drug-drug interactions, allergies, or other important aspects of medication history. Timely receipt of the medication also frequently becomes an issue with mail order purchasing.

Michigan pharmacists are sympathetic to their patients’ concerns. As health care professionals, they have come to know their patients through longstanding formal relationships. The pharmacists know that some of their patients are struggling daily with the choice between having food to eat and buying their prescriptions. As the last health professional a patient sees in the process of care delivery, the pharmacist often is the recipient of blame relative to high drug costs. Pharmacists know that they are losing patients to mail order business in the United States, as well as to purchases in Canada. Increasingly, their contact with patients is limited.

Lower costs essential to resolution

The major problems confronting community pharmacy in Michigan can be traced to one common denominator — the product cost. Until this issue is managed effectively, community pharmacy will struggle. This is a global pricing problem — one that drug manufacturers have not resolved and the U.S. government continues to sidestep.

Retail pharmacists are concerned about ensuring that patients receive safe and effective medications. Nevertheless, they recognize the external pressures (e.g., from politicians) that are driving patients to receive medications that have not been monitored for quality or safety. Given the seriousness of the issue and its effects on patients across the country, it is time for the U.S. government to advise pharmaceutical manufacturers that they must reach an appropriate solution to pricing differentials or face governmental regulation. It is reasonable to expect that such a discussion will center on who pays for research and development, and how patents and other industry assets will be addressed in countries around the world. With this action, however, the underlying issue of drug costs will be likely to receive the attention it warrants, enabling patients to continue receiving the pharmacy services of their choice.

Reference

Imported Prescription Drugs Are Not the Answer
LORI REILLY, JD
Deputy Vice President for Policy, Pharmaceutical Research and Manufacturers of America

In recent years, critics have pointed to prescription medications as a major source of health cost increases, threatening the affordability of health care in the United States. Nevertheless, while prescription drug spending is increasing, it remains a small portion of the health care, worker compensation, and economy dollar. According to the Centers for Medicare and Medicaid Services, about 10 cents of every health care dollar in the United States is spent on outpatient prescription drugs, including brand and generic medications, as well as the costs associated with pharmacies and others in the distribution chain for medications (Figure 1) (CMS 2003).

Although prescription drugs are attributed to only a small portion of the health care dollar, the issue of importation has grown in prominence. Proponents of importation have hailed it as a free market means to provide safe, lower-cost prescription drugs to consumers. Importation, however, is not a free-market principle. The savings it would purportedly generate are exaggerated, and if importation were to be legalized, the implications for maintaining the integrity of our nation’s prescription drug supply are significant.

Not a free market principle

Current law prohibiting the reimportation of pharmaceuticals into the United States is in place as a result of a multiyear congressional investigation that led to the passage of the Prescription Drug Marketing Act in the late 1980s. Every trade agreement signed by the United States recognizes the importance of domestic regulation. Both the World Trade Organization and the North American Free Trade Agreement explicitly permit governments to restrict imports for a number of important reasons, which include protection of public health and safety.

Weakening U.S. health and safety standards does not advance the cause of free trade. The U.S. Congress and successive administrations have long recognized the importance of ensuring that foreign products not manufactured or sold under market conditions are not allowed to disrupt the marketplace in the name of free trade. Importation is about importing foreign government price controls, the antithesis to free trade, and not about opening markets.

Exaggerated cost savings

Furthermore, proponents of importation have advocated abandoning current law to allow broad importation of prescription drugs because they claim it will yield cost savings of 60 to 80 percent. Nevertheless, these cost savings are exaggerated. Experts have come to the conclusion that importation will not produce significant cost savings. In fact, two Department of Health and Human Services (HHS) secretaries, a Democrat and a Republican, could not demonstrate that importation would produce cost savings or could be implemented safely.

In addition, in two cost estimates that were prepared by the Congressional Budget Office (CBO) on provisions relating to importation, savings were determined to be minimal. In CBO’s first estimate of the House- and Senate-passed Medicare prescription drug legislation on July 22, 2003, it was stated that importation of drugs from Canada, even if implemented, “would probably not produce substantial savings to the federal government” as the payer for those medicines. It did not score the bill’s importation provisions, meaning that the CBO did not make a determination that the importation provision would save the government money (CBO 2003a).

Subsequently, on Nov. 19, 2003, the CBO estimate of HR 2427, the House-passed importation legislation that would allow importation from twenty-five countries, estimated that enacting HR 2427 would reduce total prescription drug expenditures in the United States by about 1 percent during the 2004–2013 period (CBO 2003b).

The Massachusetts Group Insurance Commission administers health insurance for state employees and retirees in Massachusetts. The Commission conducted an analysis that evaluated importation from a state perspective and found very small savings. Furthermore, it found that the potential savings from prescription drug importation would not be worth the liability risks and the disruption to existing contracts (FDA News 2003).

Similarly, the National Taxpayers Union (NTU) evaluated a proposal by the state of Illinois to import prescription drugs from Canada, which indicated that savings would likely amount to approximately $0.99 per employee per month. The NTU issue brief stated: “Con-

1 Former Department of Health and Human Services (HHS) Secretary Donna Shalala concluded on Dec. 26, 2000, that it was “impossible...to demonstrate that it [importation] is safe and cost effective.” Similarly, HHS Secretary Tommy Thompson, citing an analysis by the U.S. Food and Drug Administration on the safety issues and analysis by his planning office on the cost issues, decided not to “sacrifice public safety for uncertain and speculative cost savings.”
contrary to the governor’s claims, this publicly available data suggest that Illinois will save zero to a small amount of money from importing drugs from Canada” (NTU 2003).

Also, the Congressional Research Service has stated, “It is unclear at this point whether these changes in the law [changes to legalize importing of prescription medicines] would have a long-term impact on the cost of pharmaceuticals to U.S. consumers primarily because the determinants of drug prices are so diverse, interdependent, and labile” (CRS 2003).

Safety concerns
In terms of health and safety risk, the U.S. Food and Drug Administration has reiterated its concerns on numerous occasions. In addition, Canada has stated it will not guarantee the safety of drug imports. According to Peter J. Pitts, FDA associate commissioner for external relations, “The Canadian government is now on record saying they cannot guarantee the safety and effectiveness of drugs not legally exported into the United States. The Canadian position reinforces our position that bringing in any medical products from outside our borders that are not FDA approved is inherently risky and dangerous” (Kaufman 2003).

The FDA and the U.S. Bureau of Customs and Border Protection recently conducted a series of spot examinations of foreign drug shipments through the mail into the United States. The examinations illustrated that drugs entering the United States are often unapproved medications, including potentially dangerous drugs, as well as counterfeit drugs. According to the FDA, “Of the 1,153 imported drug products examined, the overwhelming majority, 1,019 (88 percent), were violative [sic] because they contained unapproved drugs. Many of these imported drugs could clearly pose safety problems (FDA 2003a).”

Opponents of importation
Recognition of these risks is extensive. A wide range of organizations including the research-based sector of the pharmaceutical industry opposes importation. Prominent examples include the AMA, the National Alliance for the Mentally Ill, the Kidney Cancer Association, the National Prostate Cancer Coalition, the U.S. Chamber of Commerce, the National Association of Manufacturers, the Generic Pharmaceutical Association, and the National Association of Wholesaler-Distributors, among hundreds of others.

Pharmacists and pharmacies have also questioned the safety of illegal drug importation. According to Craig Fuller, president and chief executive officer of the National Association of Chain Drug Stores, “Rapid growth of the illegal importation of prescription drugs from Canada and other countries into the United States is putting patients at risk” (NACDS 2003).

Although some have proposed mandating the use of anticyounterfeiting technology as a means to guarantee the safety of imported medications, technology is not a silver bullet. According to the October 2003 FDA Counterfeit Drug Task Force Interim Report, “There is no single ‘magic bullet’ against the growing number of sophisticated [drug] counterfeiters” (FDA 2003b).

The only way to keep the U.S. drug supply safe is to keep the pharmaceutical distribution system closed to imported drugs. There are other solutions for patients who cannot afford their medication. Late last year, President Bush signed historic legislation that, for the first time, will provide prescription drug coverage to Medicare beneficiaries. Furthermore, there are patient-assistance programs for patients not eligible for Medicare, which last year provided medications free of charge to an estimated 6.2 million patients. More information on these programs can be found at: «www.helpingpatients.org».

References


Blue Cross Blue Shield (BCBS) of Michigan is a not-for-profit health care company that offers managed traditional Blue Cross Blue Shield, preferred provider, and managed care benefit programs to 4.8 million members. BCBS Michigan provides pharmacy benefits to 3.1 million lives. In 2002, BCBS Michigan reimbursed 44 million pharmacy claims, totalling $2.3 billion. Prescription drug payments per member have increased by 65 percent since 1998, rising from an annual average of $444 in 1998 to $731 in 2002.

Because total U.S. drug spending is expected to continue increasing by double-digit percentages — with projected annual increases ranging from 14 to 18 percent during the next 5 years — we as a nation must seek ways to manage this trend while maintaining program quality. The safety of our members’ prescriptions is our foremost concern as a health plan. We at BCBS Michigan know that while it is important to keep costs low, it is crucial to have reasonable assurances regarding the safety of the drug being used.

Although we do not look outside of the United States in attempting to lower our drug costs, in some cases, BCBS Michigan does offer reimbursement for claims received for drugs purchased in foreign countries. Typically, such claims are filled by those who live outside of U.S. borders but work for U.S.-based companies. Like most other health plans, BCBS Michigan also reimburses members for prescriptions that are obtained outside the United States because of medical emergencies. Such claims (totaling only about 1,500 per year) are reimbursed at the approved reimbursement amount less any portion of the set member cost share. To qualify for reimbursement, these drugs must be available in the United States and approved by the U.S. Food and Drug Administration.

Mail order pharmacies

BCBS Michigan provides no reimbursement for members who use mail order pharmacies outside the United States. We have an exclusive mail order arrangement with a pharmacy benefit manager, and our members must use the PBM network for coverage of mail order prescription drugs. Most of our members use our network pharmacies exclusively, because they know that using a participating pharmacy lowers their out-of-pocket costs. We have our own retail pharmacy network in Michigan, which includes nearly all the 2,000 pharmacies in Michigan, in addition to a network of 50,000 pharmacies outside the state to serve our members who travel or live outside our borders.

Cost sharing

The average member copayment for an individual who is enrolled in one of our health plans today is about $10, which is not at a level that would drive many members, if any, to seek better deals outside the United States. Nevertheless, as purchasers move toward benefit designs that shift more cost-sharing to members, the members may show more interest in crossing the border to obtain prescription drugs. For example, in response to steep percentage increases in drug prices, employers have been changing copayments for members from flat amounts to percentage coinsurance based on what our health plan pays for the drug. As the cost of the drugs increase, so does the member’s out-of-pocket cost. Additionally, triple-tier drug benefits, which can sometimes require a copayment of $60 for a product on the top tier, are growing as a purchaser choice. Although only 2 percent of our members today have triple-tiered drug plans, an increase in this number could spur members’ interest in reimported prescription drugs.

Reimportation and savings

In addition to questions of safety being raised by the FDA and others, there also is the question of whether actual savings can be realized by U.S. consumers should drug reimportation be made legal. For instance, pharmaceutical manufacturers may restrict product sales to Canada, so a significant share is then reimported into the United States. Canada’s market is much smaller, amounting to only $14.6 billion (CHI 2003), versus the $211 billion U.S. market (Long 2004).

In addition, the pricing policies of different governments sometimes result in higher costs than are found in the United States. Nonetheless, Connecticut Democratic Rep. Rosa DeLauro claimed, during the debate on HR 2427, the Pharmaceutical Market Access Act (aka the Gutknecht-Emanuel bill), that U.S. consumers could save $600 billion over 10 years if they had access to foreign markets. Contrary to this, the Congressional Budget Office, in its analysis of the Medicare Prescription Drug and Modernization Act of 2003, reported that drug reimportation from Canada would probably not produce substantial savings.
These different perspectives leave us with many questions about potential savings. Even so, we know that U.S. employers and purchasers usually pay more for drugs than do people anywhere else. Given that many of these companies are international players, high drug costs put them at a competitive disadvantage in the international marketplace. In underdeveloped countries, there is still a need for flexible pricing, because those economies cannot afford drugs priced like those in this country. Yet this consideration should not overshadow the need for a more level playing field with respect to drug pricing.

At a recent meeting of insurance executives and congressional leaders, a legislator described reimportation as “a bad fix for an even uglier problem.” At BCBS Michigan, our position on reimportation is neutral. It is certainly not a panacea. Yet we can expect reimportation to be supported by some purchasers and consumers — and even state and local governments — as a way to help control rising drug costs, unless other viable solutions to rising drug costs can be found.

References

Why are Americans reimporting prescription drugs? The answer is simple: they see lower prices as a way to reduce their substantial out-of-pocket burden for prescription drugs. Consider these facts:

- Americans, particularly older Americans, need many prescription medications. On average, individuals 65 years of age or older fill prescriptions 25 times per year (Briesacher 2002). Many fill prescriptions much more frequently, while others do not fill prescriptions due to cost (Safran 2002).
- The typical Medicare beneficiary is projected to incur an average of $2,322 in total prescription drug costs in 2003, $999 of which will be paid out of pocket. Medicare beneficiaries without prescription drug coverage are projected to incur an average total prescription drug cost of $1,356, all of which is paid out of pocket (Kaiser 2003).
- Drug prices are partially responsible for driving these spending levels up. Prices in the United States for many brand-name drugs are quite high relative to prices for identical products sold in other countries. Americans — particularly those who lack adequate prescription drug coverage — have begun looking to Canada or other countries for more affordable drugs with greater frequency.

The accompanying table provides examples of cost savings from which U.S. consumers may benefit by purchasing prescription drugs in Canada. Average prices charged for four drugs widely used by the elderly on a particular day (March 12, 2003) were compared between four U.S.-based mail order pharmacies and four Canadian mail order pharmacies. Substantial differences were noted, with prices in the United States being higher by approximately 13 percent to more than 50 percent. These price discrepancies will vary from pharmacy to pharmacy, day to day, and drug to drug. In fact, many generic drugs are less costly in the United States than in Canada. The pattern of higher U.S. drug prices relative to Canadian prices — particularly for brand-name drugs — however, is well established (Gross 2003) and explains the apparent eagerness of American consumers to fill their prescriptions through Canadian pharmacies.

### AARP on drug reimportation

Currently, AARP does not encourage reimportation of prescription drugs because it is illegal. Although AARP recognizes that many Americans are buying drugs from Canada or through Internet sites from a host of foreign countries, it has neither endorsed such transactions, nor sponsored bus trips to Canada for drug purchasing or knowingly accepted advertising in its publications from sources participating in reimportation, and it has not knowingly engaged in any other activities to support actions that would violate federal laws on reimportation. Also, AARP does not allow Internet sites that offer foreign-bought drugs to Americans to imply that AARP supports their endeavors.

Nevertheless, AARP does advocate changes in legislation that support the legalization of reimportation. AARP believes that reimportation could help slow the double-digit increases in drug costs that Americans face. AARP also holds the view that policy changes must be accompanied by measures to ensure confidence in the safety and integrity of reimported medications. For example, the U.S. Food and Drug Administration should be given the resources and authority to ensure that these drugs are safe, using technological and other safeguards to do so.

AARP’s interest in ensuring safety is focused not only on individuals who purchase drugs in Canada but also on those who purchase drugs from any mail order pharmacy, including those in the United States. AARP supports greater state and federal coordination in regulating all mail order pharmacies, considering that many of the safety problems attributed to Canadian mail order pharmacies are equally relevant to domestic entities.

AARP believes that safety concerns can be minimized by restricting the legal source of reimportation to licensed

### TABLE Comparison of U.S. and Canadian mail order pharmacy prices for selected drugs purchased on March 12, 2003*

<table>
<thead>
<tr>
<th>Drug/Dose/Quantity</th>
<th>U.S. ($)</th>
<th>Canada ($)</th>
<th>Savings (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Amlodipine (Norvasc) 10 mg/100</td>
<td>184.78</td>
<td>161.16</td>
<td>12.8</td>
</tr>
<tr>
<td>Atorvastatin (Lipitor) 20 mg/90</td>
<td>286.74</td>
<td>164.78</td>
<td>42.5</td>
</tr>
<tr>
<td>Celecoxib (Celebrex) 100 mg/100</td>
<td>150.27</td>
<td>72.27</td>
<td>52.0</td>
</tr>
<tr>
<td>Paroxetine (Paxil) 10 mg/30</td>
<td>74.21</td>
<td>51.26</td>
<td>30.9</td>
</tr>
</tbody>
</table>

*Average prices in U.S. dollars posted for four drugs from U.S. and Canadian Web sites.

SOURCE: BARRY 2003
Canadian pharmacies and wholesalers for a defined period of time. Canada is already the source of considerable de facto reimportation, and safety violations appear to be minimal in extent and insignificant in nature. By allowing drug reimportation from Canada for a defined period of time, federal agencies could assess the impact that reimportation has on quality of care, access to appropriate medicine, and the magnitude of cost savings.

**Legalization of reimportation**

The most prevalent criticism used to argue against legalizing drug reimportation revolves around the issue of drug safety. Yet, the status quo is not without substantial safety risk. Improving safety standards for legal reimportation is a response to the reality that tens of thousands of Americans now are purchasing drugs from Canada, without specific reimportation regulations in place. These individuals may not be able to distinguish reputable Canadian pharmacy Web sites from other Web sites that are masquerading as Canadian pharmacies. In contrast, under legal reimportation, U.S. pharmacies and wholesalers could establish relationships with reputable and accredited Canadian retailers and wholesalers, similar to how they currently establish relationships with U.S. wholesalers.

Furthermore, maintaining the status quo poses a safety risk for individuals who do not take their prescribed medications because they simply cannot afford them. For example, individuals who do not take their prescribed medications for high cholesterol, hypertension, or heart disease are putting themselves at risk for adverse health outcomes. Making medication more affordable reduces that risk considerably.

The extent of the alleged risks of reimportation also should be addressed. To gain an understanding of this issue, American policymakers can study the experience in the European community where reimportation — known as parallel importing — is not only legal but also sometimes encouraged as a public policy tool. Americans should investigate the rate of reimportation in these countries; the safety problems that exist, if any; and government management of safety concerns.

**Additional measures to lower drug costs**

Drug reimportation, however, will not resolve the problem of high drug costs and drug affordability in the long term. AARP recognizes that the benefits of reimportation are uncertain, because the extent to which pharmacies would pass on lower prices to consumers is unknown. Furthermore, how available Canadian drugs will be to U.S. consumers is also unknown, particularly if manufacturers are successful in restricting the ability of Canadian pharmacies and drug wholesalers to sell drugs to Americans by threatening to cut off supply.

In addition, AARP recognizes that a broader range of rational cost-containment mechanisms is needed. For example, comparative information relative to drug effectiveness would allow third-party payers, physicians, pharmacists, and consumers to better understand when to use a newer, more costly drug and when to use an older, far less expensive drug that may be equally — or even more — effective. Such information could not only reduce pharmaceutical costs but also increase the availability of safe and effective pharmaceutical treatment.

Finally, AARP’s highest priority for increasing affordability, of course, is a Medicare drug benefit. After all, although prices tend to be lower in Canada and in other countries compared with the United States, most people in these countries, particularly those older than 65, have good coverage for their prescription drugs. Furthermore, many Medicare beneficiaries lack the benefit coverage to pay for their drugs. This is why AARP is working so hard for a meaningful drug benefit in Medicare.

**References**
