

Impact of drug importation on community pharmacy and patient care

Marv D. Shepherd

With the political powers shifting in both congressional houses, many pharmaceutical issues have resurfaced in the 110th Congress. One of these is legalization of drug importation. Many Democrats and Republicans have already stated that this is a high-priority item.¹ In the first 60 days of the First Session, two bills were introduced that would legalize drug importation (Senate Bills 251 and 242). At the state level, Connecticut, Kentucky, Maryland, and Oklahoma have bills pending on drug importation. Over the years, various polls have indicated that the majority of the American public favors drug importation.²⁻⁵

As Americans consider the wisdom of drug importation, the point needs to be made that the debate about importing drugs is not about importing drug products; it is about taking advantage of other countries' governmental drug price controls. In other words, it is about importing another country's drug price controls, not about importing pharmaceuticals.

Many believe the answer to combating high U.S. drug prices is to have approved or "authorized" foreign pharmacies sell drugs directly to Americans or have "authorized" foreign drug wholesalers sell drugs directly to either U.S. drug wholesalers or to U.S. pharmacies. The theory is that drug importation will enhance U.S. price competition and lower U.S. drug prices.

Such a change in U.S. policy would have enormous effects on all pharmacy sectors. Most of the attention has focused on the drug price differentials between the United States and other countries. Some attention has been given to the impact of drug importation on the pharmaceutical research industry, its

research productivity, and drug safety issues such as the increased potential of receiving substandard, counterfeit drug products or products that do not have FDA approval.

In this Viewpoint, I would like to bring the profession's attention to the potential impact of drug importation on community pharmacy practice.

Drug importation choices and tiers for U.S. consumers

Many community pharmacists support drug importation because they believe it will reduce product costs. Community pharmacists interact with patients who have limited resources to pay for their pharmaceuticals, and drug importation may address this issue by reducing product costs. Community pharmacists also see drug importation as a method for enhancing their competitiveness in the marketplace.

A variety of drug price scenarios can develop with the legalization of drug importation. It truly depends on the type of drug importation legislation (commercial and/or personal importation) approved by Congress and signed into law by the President. Commercial importation would allow U.S. pharmacies and/or U.S. drug wholesalers/distributors to import drugs. Currently, only pharmaceutical manufacturers can legally import drug products into this country. Personal importation would allow U.S. residents to purchase prescription drugs from an approved or "authorized" foreign pharmacy. As noted above, personal importation is illegal, but FDA is allowing U.S. residents to purchase a 90-day supply of prescription drugs and/or 50 units of a controlled substance from foreign sources.^{6,7}

With drug importation, five pricing tiers of drug products could possibly evolve, with differences in product quality risk among products in the various tiers. Risk is defined as the probability of receiving a substandard, counterfeit, or non-FDA-approved pharmaceutical product. Table 1 presents the five possible pricing and quality tiers.

Tier 1 products represent the current U.S. marketplace. Product quality, labeling, and good manufacturing practices have been FDA-approved. At least at the onset of a drug importation program, these products will likely continue to have the highest prices in the U.S. market. However, prices may decrease over time, but this is dependent on the price, quality, and safety of the imported drugs.

Tier 2 drug products are "commercially imported." That is, these products would be legally imported by approved U.S. drug wholesalers or U.S. pharmacies from "authorized" foreign drug distributors. The costs associated with these products would depend on legislative specifications for quality assurance. Most likely, the specifications would include drug quality tests, approved U.S. labeling, and the assurance of proper drug handling throughout the product's distribution system. Since the added quality assurance and labeling costs are difficult to predict, the product price is also difficult to predict. However, these products will probably cost less than tier 1 products. However, how much lower the price will be is unknown. Some worry that relabeling costs, the required "quality assurance" measures, and profit taking by middlemen may be excessive and could therefore offset consumer savings.⁸ In terms of product quality risk, some products may not be FDA-approved, as is currently the case with imported Canadian drugs. Again, this will depend on legislative requirements.

Relabeling requirements for imported products would present a variety of obstacles. First, products destined for foreign markets would have to be relabeled to reflect FDA requirements if they

Table 1. Risk tier, prescription drug descriptions, price indicator, and quality indicator with legalization of drug importation

Risk tiers	Product descriptions	Prices	Quality assurance concerns
1	FDA-approved brand-name products made for the U.S. market	\$\$\$\$\$	High assurance of product quality. FDA-approved products = low risk.
2	Commercially imported brand-name drugs for wholesale or retail sale in United States	\$\$\$\$ ^a	Quality assurance depends on the exporting country and legislative drug testing mandates. Some products may be FDA approved; some may not. Thus, risk may be higher.
3	FDA-approved generic drugs made for the U.S. market	\$\$\$ ^a	High assurance of product quality. FDA-approved products = low risk.
4	Personally imported brand-name drugs from "authorized" pharmacies located outside the United States	\$\$ ^a	Quality assurance depends on the exporting pharmacy and exporting country standards. Quality may be depend on the U.S. quality standards and product testing mandates. May or may not be FDA approved. Risk will be higher.
5	Personally imported brand-name or generic drugs from "unauthorized" foreign pharmacies	\$	Poorest assurance of quality. May or may not be authentic products. Highest risk for counterfeit drugs.

^aImported brand-name drug products may be priced similar to or cost less than United States generic drugs.

are to be imported back to the United States. This may sound minor, except that this process eliminates the manufacturer's overt and covert anticounterfeit protection label markings. This will probably include the removal of the radio-frequency identification (RFID) tag placed on the product label. Future FDA initiatives that require drug products to have RFID tags with unique electronic product serial numbers may make repackaging and relabeling of imported pharmaceuticals difficult. Requiring U.S. products to have RFID tags but exempting imported products will only make authentication efforts more difficult. The removal of manufacturers' product labels with covert and overt markings is currently occurring in European drug trade; wholesalers from one country repack and relabel drug products to be shipped to another country. This is one factor contributing to an increase in counterfeit drugs in Europe.⁹⁻¹²

Tier 3 products are FDA-approved generic products made for the U.S. market. The reason why these drugs were included here is because of the potential

impact drug importation will have on the generic drug industry and the fact that generic products represent approximately one-half of the prescriptions sold in the United States. Generic product prices are lower than those of tier 1 products; however, for products that have an FDA-approved generic equivalent, the generic drug product may or may not cost less than the imported brand-name product. Again, this depends on the requirements of the drug importation legislation. If the costs of the imported drug along with the product quality assurance measures and relabeling are low, then the possibility exists that imported brand-name drug products could compete directly with U.S. generic drug products.

Governmental price controls could result in the price of the foreign-sourced generic drug being less than the U.S. generic product. This would occur early in the generic drug product's life cycle, when little or no competition is present from other generic drug companies. However, as generic drug competition increases, the price of the product would continue to drop; this is why older generic

drugs are cheaper in the United States than in Canada.

To illustrate this problem, I compared the prices of brand-name simvastatin (Zocor—Merck; 20 mg, 100 tablets) and generic simvastatin in the United States and Canada. In July 2006, Zocor's patent expired and the first generic simvastatin appeared on the U.S. market. The average U.S. brand-name price in July 2006 was \$461.93 (based on weekly data from five prominent U.S. Internet pharmacies during that month). The average Canadian price for Zocor was \$259.08 (based on eight Canadian Internet pharmacies in July 2006). In July 2006, the average price for generic simvastatin was \$413.25 in United States and \$151.62 in Canada. Prices for the same commodities in February 2007 were as follows: U.S. brand name, \$454.04; U.S. generic, \$335.44; Canadian brand name, \$257.49; and Canadian generic, \$137.43. Of note, the Canadian prices in this example would most likely be higher for Americans with legal importation because of the cost of safeguard measures. At any rate, the Canadian brand-name drug remained

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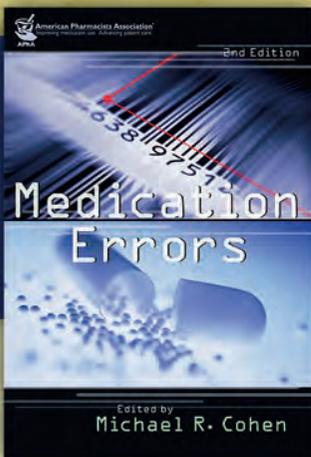
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cheaper than the average U.S. generic simvastatin. No one knows which product U.S. consumers would purchase if the Canadian drugs were legally available, but U.S. insurance carriers would probably opt for the Canadian generic drug. In the future, the U.S. generic drug price for simvastatin is anticipated to be lower than the Canadian price.

With the legalization of drug importation, U.S. generic drug products would not only be competing with the U.S. brand-name product but also with imported brand-name and generic drugs. The high U.S. generic drug margins during the exclusivity period may be severely threatened by such competition. U.S. generic drug manufacturers would have to carefully evaluate if it would be worthwhile to develop and seek FDA approval for the generic drug knowing that consumers may be able to obtain the brand name drug at a lower cost from a foreign source. Generic drug manufacturers' "incentive" provided by the 180-day exclusivity period would be threatened by drug importation. This also explains why, in some countries, "government fixed" brand-name drug prices stifle the market for generic drug products.^{13,14}

Tier 4 products are "personally" imported brand-name drug products from approved or "authorized" foreign pharmacies. These are products that the American consumer can legally purchase directly from an approved or "authorized" out-of-country pharmacy. Because the middlemen are bypassed by buying directly, these drugs might be cheaper than products from the above tiers, especially when compared with products from tiers 1 and 2.

The quality of products from tier 4 may have added risk; however, this depends on the exporting pharmacy, U.S. legislative mandates, and regulations of the exporting country. These "authorized" pharmacies hopefully would be monitored to ensure drug quality. How this would be accomplished is unknown. Such a monitoring system would certainly add cost to the governmental importation program but probably would not affect the drug cost for the consumer.

Without some kind of monitoring system, the threat of substandard or counterfeit drugs entering directly into U.S. homes exists. A good example of the repercussion of the lack of monitoring is what happened in the summer of 2006 when Americans were purchasing what they thought were authentic brand-name products from Canada but received counterfeit drugs from supposedly "high quality" Canadian pharmacy Web sites.¹⁵ The Canadian pharmacies were transferring the prescription orders to pharmacies located outside of Canada. When consumers purchase directly from foreign pharmacies, the safety and quality checks for imported drug products become much more difficult. Thus, the risks of receiving a substandard product would likely be much higher for tier 4 products than for those in tiers 1 through 3. However, tier 4 drug prices would be much lower than those for tiers 1 through 3, mainly because of "no profit taking" by middlemen and by the elimination of costs associated with middlemen in the distribution channel. Tier 4 products would be very attractive to U.S. consumers and a source of increased competition for U.S. community pharmacies.

Tier 5 drug products are distributed from foreign drug sellers/pharmacies that are not "authorized" or approved for drug importation. Even with legalization of drug importation, Americans will continue to access a wide variety of medicinal products from "unauthorized" pharmacies from all over the world via the Internet. In fact, this may be enhanced with the passage of drug importation legislation. As stated above, many products from these sources have been found to be substandard or counterfeit.¹⁶ Many of these distributors use rogue Web sites, and many sites do not require prescriptions for purchasing drugs, even for controlled substances. Obviously, drug products from these pharmacies have the greatest risk of being counterfeit but will probably cost less, which consumers will find attractive.

Impact of commercial importation on community pharmacies

U.S. community pharmacies are extremely vulnerable to problems brought on by drug importation laws. Obviously, the impact on U.S. community pharmacies depends on the specifics of such legislation. If the drug importation legislation allows only for "commercial" importation and not "personal" importation, then the impact will be less. However, this depends on many other factors. With commercial-only importation, many community pharmacy operations will relish the arbitrage opportunities. However, one needs to be very careful because other competitive issues will appear with commercial importation.

For example, U.S. insurance companies and PBM firms are very likely to expand their operations and pharmacy networks to include pharmacies outside the United States. However, before they could do this, they would need to determine if the risks of using imported medications were offset by cost advantages. The possibility exists that if the health risks were too great, insurance companies and PBM firms would remain with FDA-approved products within the United States. If they believe the risks are low, however, pharmacies outside the United States could very well be added to their prescription drug benefit network. This certainly would present difficult competition for U.S. pharmacies, especially those located near the borders. Furthermore, one can expect more buses filled with Americans crossing the border to purchase prescription drugs. In addition, many managed care firms will probably open mail-service operations or set up contracts with existing foreign mail-service pharmacies. This added competition could have major adverse effects on U.S. community and mail-service pharmacies.

Another possibility is that U.S. community chain pharmacies will move their product purchasing, product sourcing, and some stores outside the United States to take advantage of the foreign government-regulated drug prices and reduce

the number of middlemen within the United States. These firms will not only ship drugs directly to their stores from outside the United States but will move their mail-service customers to their foreign-based operations and encourage U.S. residents to visit their out-of-country outlets. Some U.S. chain-store and mass-merchandise companies are already in place to take advantage of this opportunity. Also, some U.S. drug-buying groups may move "offshore" to take advantage of the lower acquisition costs.

Some have proposed that Americans should be able to get all or a major share of their medications from Canada. The problem with this scenario is that Canada does not have the drug supply to meet the needs of Canadians and a large contingent of the U.S. population. Based solely on the number of prescriptions dispensed, the Canadian annual supply of drugs would be exhausted in less than 2 months if all U.S. residents purchased their drugs from Canada.¹⁷ If one-half of U.S. prescriptions were dispensed in Canada, it would only take 70 days for the number of prescriptions to equal Canada's 2005 annual prescription drug volume.

Using today's realities and a practical perspective, Canada is unlikely to be able to meet the prescription drug demands for large numbers of Americans. The U.S. population is 10 times larger than that of Canada. The health and welfare risks to Canadians would be monumental if a vast number of U.S. residents began obtaining their prescription drugs from Canadian sources. Politically, it is very dangerous to have Americans drain the Canadian drug supply, not to mention increase the health risks for Canadians. The problem of not having the drug supplies to meet demands will be exaggerated if U.S. pharmaceutical manufacturers limit their pharmaceutical supplies to meet just the needs of the Canadian population. This has occurred in Europe as a result of parallel trade initiatives. Drug manufacturers limit their supplies to meet just one country's needs, plus perhaps 5% to 10%. If this were to hap-

pen with Canada, it is expected that drug shortages will appear quickly in community and hospital pharmacies throughout Canada. Even if supply limitations were not initiated, the Canadian drug distribution system infrastructure would have to be greatly expanded to meet the increased demands. The importation of pharmaceuticals from only Canada presents a grave threat to Canadians. Canada does not have the capacity or the infrastructure to be the "drugstore" for the United States. Furthermore, Canadians do not want U.S. residents raiding their medicine cabinet.¹⁸

Impact of 'personal' drug importation on community pharmacy and patient care

If "personal" drug importation were legalized, the impact on U.S. community pharmacies could be disastrous. The concern is that U.S. community chain or independent pharmacies would not be able to compete with foreign pharmacies, which have government-regulated drug prices. Basically, U.S. community pharmacies would probably pay more for the drug product from their wholesalers than what consumers would pay for the product from a foreign pharmacy. Even if U.S. community pharmacies could legally import drug products, consumers would be able to obtain the same drug at a lower price by going directly to a foreign pharmacy.

To some extent, this competitive situation exists today for those U.S. pharmacies located along Mexican and Canadian borders. However, the impact of foreign competition on U.S. community pharmacies has been mitigated since many third-party prescription drug plans will not currently cover drug products originating from outside their pharmacy networks, and of course foreign pharmacies are outside such networks. Another reason is that patients' drug copayment requirements may be lower than the foreign drug product price. However, this may change with the legalization of drug importation. It is relatively safe to assume that third-party payers (insurance firms and PBMs)

will expand their pharmacy networks to include pharmacies outside U.S. borders. If this occurs, U.S. community pharmacies will be competing not only locally but also with pharmacies outside the United States. As can be seen, the threat to community pharmacy survival is enhanced with personal importation.

One major problem is that our state or federal governmental agencies have no control over pharmacies located outside the United States. If problems develop with the out-of-country pharmacies, where are the legal rights of the U.S. citizen? As stated, pharmacies outside the United States are not under the jurisdiction of a U.S. resident's state board of pharmacy; therefore, it would be difficult for a U.S. resident to seek damages from a pharmacy located in France, Germany, South Africa, or Canada. In fact, according to Canadian Web sites, many Canadian Internet pharmacies require U.S. residents to waive their rights before dispensing prescriptions.

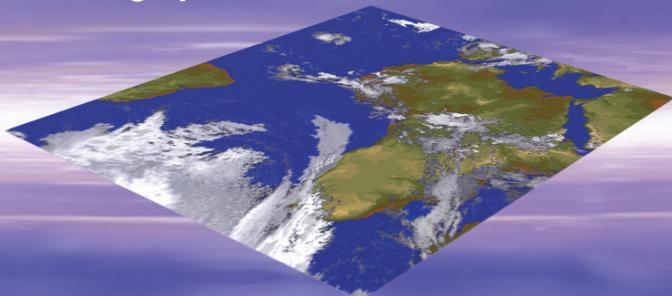
Patient care would also be devastated by personal drug importation. Continuity of care, monitoring of patients, and the personal interaction of patients with local community pharmacists would be threatened. It is difficult to imagine personal drug services being provided to U.S. patients from pharmacies located in the United Kingdom, France, or Greece. Plus, with some patients purchasing drugs both from out-of-country pharmacies and at their local pharmacy, U.S. pharmacists, as well as the foreign pharmacists, will most likely not have a complete drug profile of the patient. This raises the risks of adverse drug events. The possibility exists that the added health care costs associated with the lack of or disruption in patient care will offset any cost savings generated by a drug importation plan.

Conclusion

One can argue that drug importation presents an array of choices for the American public for obtaining prescription drugs. It opens a "global" competitive environment and theoretically

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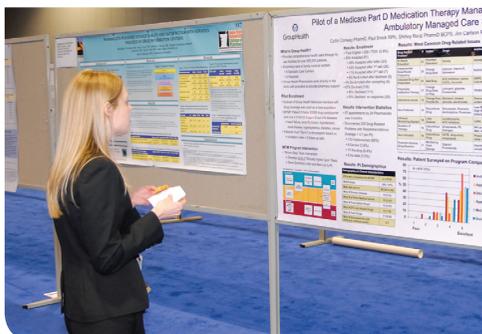
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presents cost savings to the American public. However, the amount of these potential cost savings is unknown, and comparing drug prices between countries is an oversimplification and does not depict an accurate picture of the true costs.

Drug importation also puts the patient at risk by potentially hampering continuity of care and drug therapy management. Americans could be placed at an increased risk of receiving substandard drug products, depending on the type of drug importation and extent of product quality-control regulations.

The risk to the livelihood of community pharmacy operations is noteworthy, and disruptions in this arena could have profound effects on the American public. Pharmacists are the most accessible health care providers in the United States, but accessibility could be dramatically reduced if the pharmacist provider is located outside the United States

It is difficult to predict which one or more of the five tiers will prevail. Aspects of each may be seen in the future. Past importation legislation has been approved by Congress but not signed into law by the President. Drug importation legislation probably will be approved again by Congress, but whether the President will sign the bill is unknown. It depends on the political schema of the time.

It is not too late for U.S. community pharmacists, owners, and pharmacy associations to get involved and monitor the progress of drug importation legislation. This is no time to sit back and watch the deliberations. I encourage you, state pharmacy associations and societies and national pharmacy associations leaders, to take an active role in this legislative agenda. Community pharmacists have

much to offer legislators and their constituencies. More importantly, community pharmacy has much to lose if you do not get involved.

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