Institute For Policy Innovation
IPI Ideas
Innovative Insights on Today's Policy Debates
NO. 19 FROM THE IPI CENTER FOR TECHNOLOGY FREEDOM APRIL 2003

The Ethical Dilemmas of Prescription Drug Reimportation

By Dr. Merrill Matthews Jr.

The reimportation of prescription drugs—in which drugs made in the U.S. and sold and shipped to other countries are then sold and shipped back (reimported) to the states—is a growing political issue.

Seniors are going to Canada and other countries to buy prescription drugs at lower prices and are bringing them back to the states. Moreover, there are an estimated 80 online pharmacy Web sites in Canada that sell prescription drugs, many of which are shipped to U.S. customers. And some doctors, pharmacies, politicians and insurers are encouraging and even helping patients to get their prescriptions from Canada.

The U.S. Food and Drug Administration (FDA), brand name prescription drug companies and many pharmacists both in the U.S. and Canada have raised a number of concerns about reimportation, citing patient safety as the primary issue. GlaxoSmithKline, one of the largest pharmaceutical companies, has decided to stop selling its products to certain Canadian-based online drug vendors that are reimporting.

Reimportation proponents claim these concerns are motivated solely by profits. The truth is that reimportation creates serious ethical dilemmas for pharmaceutical manufacturers that are not easily resolved.

The Making of an Ethical Dilemma. An ethical dilemma arises when a person, company, organization or country is forced to choose between some established law or principle and the consequences that could result from setting aside that law or principle.

Brand name drug manufacturers believe they are serving mankind by making life-saving drugs and ensuring that people who need their products have access to them.

But what if the wholesalers buying the products—for example, online pharmacies—unethically or illegally abuse the process? What if the quality of the drugs is compromised? Can the risks to patient safety outweigh the benefits of getting drugs to those who need them?

Ethical Dilemma #1: When Is It Right to Break the Law? It is against the law to import or reimport drugs into this country. While the FDA allows U.S. citizens traveling internationally to return with a small amount for personal use of prescription drugs that *are approved in another country but not in the U.S.,* that is the exception, not the rule.

Moreover, for practical and political reasons the FDA allows people to bring back small amounts of prescription drugs for personal use even if those drugs have been approved in the U.S. But that doesn't mean it's legal; the law is just not rigidly enforced.

Thus, U.S. politicians who encourage seniors—even help them arrange for buses—to travel to Canada and buy prescription drugs are helping those Americans break the law. Bizarrely, some U.S. politicians are threatening to punish any drug company that chooses not to sell to Canadian pharmacies that break U.S. law.

Reimportation supporters have placed pharmaceutical manufacturers in a very difficult position: Should the companies sell their products to vendors they know will illegally reimport the drugs? If not, how should they respond to the accusations of politicians and advocates who claim the companies are uncompassionate?

Ethical Dilemma #2: When Is It Right to Undermine International Agreements? To protect its intellectual property (IP) the motion picture industry has developed a system of DVD region codes, based on an agreement between content producers and consumer electronics

manufacturers. Region codes permit DVDs manufactured for sale in one region of the globe to be played only on DVD players manufactured for sale in that same region, in essence preventing large-scale reimportation. The pharmaceutical industry can't incorporate region codes; the only way to protect its IP is through laws and agreements.

The U.S. is a signatory to the 1994 TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights), which established international rules giving patent owners the right to prevent others from making, using, selling or importing patented products without the consent of the patent holder. Canadian pharmacies that reimport U.S. manufactured drugs without the consent of the patent holder undermine this agreement.

Reimportation proponents would have the drug companies disregard international law so that a small number of U.S. citizens can get their prescriptions at lower prices. Yet if the brand name companies ignore reimportation, they could undermine international agreements and set a precedent for the illegal reimportation of other types of intellectual property.

Ethical Dilemma #3: How to Ensure Patient Safety? The World Health Organization estimates that roughly 10 percent of the world drug supply is counterfeit. Fortunately, the vast majority of those counterfeits are outside of the U.S., in countries with much less drug monitoring.

But that would change with widespread reimportation.

A recent report from the Royal Canadian Mounted Police stated that Canada has an "established counterfeit industry," in part because of lighter penalties, and that counterfeiting in Canada has reached an "epidemic."

A San Diego-based agent for the U.S. Drug Enforcement Agency (DEA) has told reporters, "About 25 percent of the prescription drugs we see coming across the border are counterfeit . . . of the remaining 75 percent, the vast majority of those are not from FDA-approved sources. When you cross the border to buy prescription drugs, you are basically taking your chances."

What are some counterfeiters' tactics? They:

- Mix placebos with real pills in the same bottle;
- Dilute drugs; and,
- Allow drugs to be exposed to excessive heat or cold.

It is virtually impossible for brand name manufacturers to monitor their products after they leave the U.S. Yet if a U.S. citizen who reimported a brand name drug were harmed, the drug manufacturer would be widely criticized—and, no doubt, sued—for not doing enough to protect patient safety.

Those who work in the medical field know that protecting patient safety is the ultimate ethical principle. The threat to patient safety grows as the number of individuals and companies reimporting prescription drugs increases. Is it ethical or prudent for a drug manufacturer to knowingly sell to a vendor outside the U.S. who can't assure quality and who intends to send the drugs back into the U.S.?

Perhaps more importantly, why are some politicians less concerned about their constituents' safety than are the companies that manufacture the drugs, as well as several secretaries of the Department of Health and Human Services (both Republicans and Democrats) who have strongly opposed reimportation?

Ethical Dilemma #4: What to Do about "Compulsory Licensing"? Pharmaceutical manufacturers want to make their products available both in the U.S. and abroad. But if a drug company doesn't agree to a lower price mandated by a foreign government, many of those countries allow their generic manufacturers to copy the drug and sell it. It's called compulsory licensing.

Americans would never stand for a criminal justice system in which a thief could walk into a home and demand the homeowner sell his possessions for whatever price the thief was willing to pay, and if the homeowner refused the thief was free to take the items and sell them for a profit.

That is precisely what some countries do to drug manufacturers. Yet it is the drug manufacturers, not the countries, that are criticized.

Conclusion. Reimportation forces drug manufacturers to face numerous ethical dilemmas. Although some politicians and "consumer advocacy" groups are willing to ignore the law, international agreements and patient safety for their own self-interests (the politicians want votes and the advocacy groups want cheaper prices), the pharmaceutical manufacturers don't have that luxury.

Dr. Merrill Matthews Jr. is a Visiting Scholar at the Institute for Policy Innovation.

Direct all inquiries to:

Institute for Policy Innovation
250 South Stemmons, Suite 215
Lewisville, TX 75067

(972) 874-5139 [voice]
(972) 874-5144 [fax]

Email: **ipi@ipi.org**
Website: **www.ipi.org**