CHEAPER DRUGS? REIMPORTATION AND ITS RISKS

BY
DANIEL K. CRAY
RODNEY E. VanAUSDAL

I. INTRODUCTION

"NEWS FLASH: PRESCRIPTION DRUG PRICES OUT OF CONTROL!"

The images and themes from last fall's election campaign are still fresh in our collective mind. Al Gore questions why the cost of his mother's medication is higher than the cost of his dog's medication. Congressional candidates in border states lead buses full of senior citizens on road trips across the northern and southern borders of the United States to purchase their prescription drugs in Canada or Mexico. Consumer advocates display vials of "identical" medication in each hand – one purchased domestically and one purchased overseas – while decrying the difference in price and demanding action!

Against this backdrop, congress enacted the "Medicine Equity and Drug Safety Act of 2000" ("MEDS Act"), 2000 H.R. 5426, 106 H.R. 5426, incorporated by reference in 106 P.L. 387. At present, the measure is largely symbolic; some commentators have suggested somewhat cynically that Congress enacted this impractical, unworkable legislation solely to avoid being accused of doing nothing with respect to prescription drug costs. Yet, even the supporters of this legislation acknowledge that in its current form, this legislation may never accomplish its intended goal of increasing the availability of more affordable prescription drugs, and that even under the best of circumstances, the impact of this legislation is years away. Still, regardless of the

ultimate fate of this particular legislation, the renewed attention being devoted to the "reimportation" of prescription drugs, along with the economic pressures that will continue to encourage individual consumers to reimport their own prescription drugs, make it likely that the importance and significance of this issue will continue to increase as time passes.

In this article, we examine the historical development of drug reimportation legislation and regulation, the risks created by this product distribution system, and some common sense solutions for limiting these risks.

II. REIMPORTATION: A HISTORICAL PERSPECTIVE

By technical definition "reimportation" of prescription drugs into the United States would imply a process by which prescription drugs are imported once, then exported, and then "reimported." However, in common usage, the term "reimportation" has come to include the distribution process by which prescription drugs are manufactured in the United States, sold directly to persons or entities in foreign countries, and then brought back into the United States for their ultimate consumption.

For many years, the price of prescription drugs in the United States has generally been higher than the price for the same prescription drugs in other countries. Governments in countries other than the United States frequently exert greater control over the administration of health care in general and prescription drug prices in particular, eliminating the impact of market factors on the price of prescription drugs by subjecting them to price controls. (See, e.g., Deneen L. Brown, "The Drugstore Right Next Door; Prices Lure Americans to Canada," The Washington Post, October 8, 2000, p. A24.) This results in an artificial though real disparity in cost between prescription drugs

sold in some foreign countries and the same drugs sold in the United States. (See, e.g., Dennis Cauchon, "Americans Pay More for Medicine," USA Today, November 10, 1999.) This disparity creates an attractive incentive for entrepreneurial free spirits to set up businesses designed to purchase U.S.-manufactured prescription drugs cheaply in foreign countries and then reimport them into the United States for sale at significantly higher prices.

Unfortunately, since these prescription drugs frequently fall outside the "safety net" of FDA regulation of transportation and storage, this reimportation process developed into a significant public health concern, and Congress was moved to action.

In 1988, Congress enacted the "Prescription Drug Marketing Act of 1987" ("PDMA") (1988 Enacted H.R. 1207, 100 Enacted H.R. 1207, 100 P.L. 293), which amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. Sections 301, 333, 353 and 381) to restrict the reimportation of drugs produced in the United States (as well as to restrict the distribution of drug samples and the resale of drugs by hospitals and other health care entities). The Congressional findings leading to the enactment of this legislation were as follows:

> (1) American consumers cannot purchase prescription drugs with the certainty that the products are safe and effective.
>
> (2) The integrity of the distribution system for prescription drugs is insufficient to prevent the introduction and eventual retail sale of substandard, ineffective, or even counterfeit drugs.
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> (3) The existence and operation of a wholesale submarket, commonly known as the 'diversion market,' prevents effective control over or even routine knowledge of the true sources of prescription drugs in a significant number of cases.

(4) Large amounts of drugs are being reimported to the United States as American goods returned. These imports are a health and safety risk to American consumers because they may have become subpotent or adulterated during foreign handling and shipping.

(5) The ready market for prescription drug reimports has been the catalyst for a continuing series of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers. Id. (2001.)

The specific reimportation amendment to the Federal Food, Drug and Cosmetic Act is codified at 21 U.S.C. Section 381(d)(1), and provides, in pertinent part:

> [N]o drug . . . which is manufactured in a State and exported may be imported into the United States unless the drug is imported by the person who manufactured the drug.

Given the significant tracking and recordkeeping requirements that were already imposed upon pharmaceutical manufacturers with respect to their products sold for consumption within the United States (see, e.g., 21 U.S.C. Section 360, 21 C.F.R. Sections 203.30, 310, 305), Congress felt confident that this legislation protected American consumers from the risk of counterfeit, adulterated, misbranded, sub-potent or expired drugs. This

legislation discouraged reimportation and distribution of foreign-bought medication within the United States other than by manufacturers by attaching severe penalties to the proscribed conduct (21 U.S.C. Section 331, 333 (2001)).

III. THE "PERSONAL USE EXCEPTION"

As is obvious from the Congressional findings described above, the Prescription Drug Marketing Act of 1987 was intended to have its greatest impact upon commercial-quantity reimporters of prescription drugs. Yet, under a strict interpretation of 21 U.S.C. Section 381(d), even individual U.S. citizens are prohibited from purchasing prescription drugs in foreign countries and importing them into the United States (except in emergency circumstances; See 21 U.S.C. Section 381(d)(2).) Historically, the FDA has been unwilling to exercise its power to enforce this statute so broadly, primarily due to limitations on FDA resources, and thus the so-called "personal use exception" has arisen. (See "Information on Importation of Drugs Prepared by the Division of Import Operations and Policy, FDA," U.S. Food and Drug Administration, Office of Regulatory Affairs, Imports (visited April 19, 2001), http://www.FDA.gov/ora/import/pipinfo.htm; see also FDA Regulatory Procedures Manual, Chapter 9, Subchapter "Coverage of Personal Importations" (visited April 19, 2001), http://www.FDA.gov/ora/compliance_ref/rpm_new2/ch9pers.html).

In practice, the FDA's "personal use exception" involves a discretionary non-enforcement of the prohibition against individual consumers purchasing their prescription drugs in foreign countries and importing them to the United States for their own personal use, so long as the quantity of the drugs generally does not represent more than a three-month supply. According to the FDA, the circumstances in which the FDA may consider

exercising enforcement discretion and refrain from taking legal action against illegally imported drugs are:

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

As emphasized by the FDA, its enforcement policy "is not, however, a license for individuals to import unapproved (and therefore illegal) drugs for personal use into the U.S., and . . . the drugs remain illegal and FDA may decide that such drugs should be refused entry or seized" (Id.).

Importantly, foreign made chemical versions of drugs that are available in the U.S. are not intended to be covered by FDA's "personal use exception" policy. (Id.). As stated by the FDA:

> For example, a person may decide that his or her FDA approved heart medication is cheaper in Mexico, and attempt to import the unapproved version of the drug from Mexico. The FDA cannot assure that such products have been properly manufactured and are effective; therefore, given that such products are available in the U.S., their use would present an unreasonable risk and the guidance would not apply (unless the person seeking their importation could establish that the drugs were needed to refill a prescription while traveling or were otherwise needed while traveling). . . .We appreciate that there is a significant cost differential between drugs available here and those in other countries. However, many drugs sold in foreign countries as "foreign versions" of approved prescription drugs sold in the United States are often of unknown quality with inadequate directions for use and may pose a risk to the patient's health. FDA

> approves a drug on the basis of scientific data proving it to be safe and effective. FDA approved labeling provides information on how and when the drug can be used to maximize effectiveness and minimize any harmful side effects. The manufacturing facilities and procedures for approved products are also carefully regulated by FDA to ensure product integrity. Since FDA cannot assure the consumer that the drug purchased in the foreign country would be the same product his or her physician's prescription is written for, we recommend the product covered by the prescription be acquired in the United States. (Id.).

Importantly, while the FDA's official position is that the "personal use exception" does not apply to drugs available in the United States, the FDA simply "recommends" that drugs available in the U. S. be obtained in the U. S. rather than in foreign countries. In practice, the FDA does not limit the "personal use exception" to drugs not available in the United States.

IV. RECENT LEGISLATION

On October 28, 2000, then-President Clinton signed into law a bill which included the "Medicine Equity and Drug Safety Act of 2000" ("MEDS Act," supra), which again amended the Federal Food, Drug and Cosmetic Act (21 U.S.C. Sections 303, 331 and 381 et seq.) to authorize a process which would relax the restrictions on the reimportation of prescription drugs under certain circumstances. The Congressional findings leading to the enactment of this legislation were as follows:

> (1) The cost of prescription drugs for Americans continues to rise at an alarming rate.
>
> (2) Millions of Americans, including Medicare beneficiaries on fixed incomes, face a daily choice between purchasing life-sustaining prescription drugs, or paying for other necessities, such as food and housing.
>
> (3) Many life-saving prescription drugs are available in countries other than the United States at substantially lower

> prices, even though such drugs were developed and are approved for use by patients in the United States.
>
> (4) Many Americans travel to other countries to purchase prescription drugs because the medicines that they need are unaffordable in the United States.
>
> (5) Americans should be able to purchase medicines at prices that are comparable to prices for such medicines in other countries, but efforts to enable such purchases should not endanger the gold standard for safety and effectiveness that has been established and maintained in the United States. Id.

In summary, once implemented, the MEDS Act would permit licensed pharmacists and wholesalers to purchase prescription drugs in a limited number of foreign countries (including Australia, New Zealand, Japan, Canada, Israel, South Africa, Switzerland and the countries of the European Union, but excluding Mexico and countries in Latin America) if the drugs are approved for sale in the U.S. by the FDA and manufactured in FDA-certified facilities (domestically or abroad), and if the drugs meet quality standards for record keeping, shipment and storage like those already imposed on drugs sold in the U.S. After purchasing these drugs at lower costs in foreign countries, the pharmacists and wholesalers could then reimport and sell these drugs in the U.S. through the existing drug distribution network. The hope and expectation of this legislation was that the free market forces of the U.S. economy would motivate these new reimporters to pass their cost savings on to consumers in the form of lower prices, since presumably the reimporter who charged a lower price for a given drug would sell more of it than a reimporter who charged a higher price. Importantly, the MEDS Act did not legalize or legitimize the "personal use exception" but simply expanded the class of authorized reimporters to include not only the drug manufacturers but also those

pharmacists and wholesalers who otherwise comply with the existing drug distribution regulations applicable to manufacturers.

The Pharmaceutical Research and Manufacturers of America (PhRMA) opposed this legislation, citing safety concerns over the potential for counterfeit drugs and the impact of reimporting price-controlled drugs on drug industry research and development. (See PhRMA, Question of the Week, January 31, 2001, visited April 19, 2001, http://www.PhRMA.org/question/archive/2001-01-31.5.phtml; see also PhRMA, Backgrounders and Facts, visited April 19, 2001, http://www.PhRMA.org/publications/backgrounders/federal/parity. In fact, 11 former FDA commissioners wrote letters to warn of the dangers of reimportation (see PhRMA, "11 Former FDA Commissioners Warn of Dangers of Drug Reimportation to American Patients," August 31, 2000, visited April 19, 2001, http://www.PhRMA/org/press/newsreleases//2000-08-31.4.PHTML and collected letters), although at least one former Commissioner later reversed course and indicated that he could support reimportation with strict oversight of the FDA. ("Former FDA Chief Now in Favor of Reimporting Rxs," Drug Topics, Vol. 144, page 10 (October 2, 2000).)

At present, the MEDS Act is in limbo. One of its essential terms required the Secretary of Health and Human Services to certify to Congress that the MEDS Act would pose no additional risk to the public's health and safety, and would result in a significant reduction in the cost of prescription drugs to the American consumer. (21 U.S.C. Section 384(l).) In a December 26, 2000 letter to President Clinton, then-Secretary of Health and

Human Services Donna Shalala stated that "serious flaws and loopholes" in the reimportation provision "make it impossible for me to demonstrate that it is safe and cost-effective." (Christopher Newton, "Shalala Won't Implement Prescription Drug Law," The Associated Press, 12/27/00.) Newly-appointed HHS Secretary Tommy Thompson, during his first official appearance before the Senate Budget Committee on March 6, 2001, responded to questions on whether he would seek to reverse former HHS Secretary Shalala's decision not to implement the legislation by stating, "We have not made a final determination yet, as to whether or not we would proceed to go ahead," and "I want to make sure we can adequately certify that [the law] will have the effect we both want." ("Thompson: Makes First Committee Appearance," American Health Line, March 7, 2001; "Rx Cost Containment Approaches Could Receive Administration Support," The Pink Sheet, Vol. 63, No. 11, p. 16, March 12, 2001.)

Current Congressional efforts to rework this law will likely keep the prescription drug reimportation cost issue in the public debate. Representative Peter Deutsch of Florida has introduced legislation entitled the "Medicine Equity and Drug Safety Act Corrections of 2001" (2001 H.R. 58, 107 H.R. 58) to correct impediments in the implementation of the MEDS Act. Senator Debbie Stabenow of Michigan has introduced legislation entitled the "Medication Equity and Drug Savings Act" (2001, S. 215, 107 S. 215), also to correct impediments in the implementation of the MEDS Act. Senator Stabenow's legislation would take the further step of permitting the reimportation of drugs by individuals for personal use, effectively legalizing the "personal use exception;" this legislation includes provisions similar to previous "personal use exception" legislation introduced by Senator James Jeffords of Vermont (1999 S. 1462, 104 S.

1462). These three bills are in various stages of the Congressional Committee process, and Congress shows no signs of dropping the reimportation issues. (See, e.g., Lawmakers Approach Bush on Reimportation," Medical Marketing and Media, Vol. 36, p. 30, March 1, 2001.) Whether reimportation of prescription drugs occurs via some modification of the MEDS Act and/or via the expanding "personal use exception," the American public and pharmaceutical manufacturers must be conscious of the risks posed by reimportation.

V. REIMPORTATION RISKS

1. Counterfeit drugs

Reimportation increases the likelihood that assertedly reimported pharmaceuticals will be in reality first-time entries in counterfeit form. While the drug regulation process in the United States inhibits counterfeiting within our borders, the same cannot be said of other areas of the globe. When certain foreign countries have not lived up to their agreements concerning protection of intellectual property rights held by extra-territorial pharmaceutical manufacturers (See, U.S. Trade Representative's Special 301 Review (2000), placing 54 countries on lists noting their failure to adhere to their agreement to establish minimum legal protection for intellectual property rights), there can be no feeling of security regarding anti-counterfeiting campaigns in those same foreign countries.

While counterfeit drugs create a **financial** risk for pharmaceutical manufacturers by loss of sales to counterfeiting companies, "reimportation" of counterfeit drugs is a

serious **health** risk to American consumers. Such drugs injure by the inclusion of unnecessary ingredients (poisons, reactive additives, etc.) and/or by the lack of necessary ingredients (failure of a counterfeit product to contain a mandatory chemical within its composition). Either way, injury to the consumer may result in unnecessary pain and suffering, medical bills, possible litigation and lengthy government assistance should the injury be debilitating.

2. Adulterated Drugs

One of the major problems with the expanding "personal use exception" is that it increases the likelihood that consumers may be injured by adulterated drugs. Most foreign countries do not have the same type of comprehensive regulation of the transportation, storage, handling and tracking of prescription drugs as exists in the United States pursuant to FDA regulations. Improper refrigeration or storage of drugs may lead to drug spoilage. The passage of time may diminish the effectiveness of reimported drugs, and consumers who are injured from subpotent or expired drugs may seek to hold the manufacturer liable.

In general, traditional strict products liability doctrine would probably not result in manufacturer liability for a "defect" that did not exist when the product left the manufacturer's control. However, the injured consumer's theories of liability are rarely limited simply to strict liability but frequently include allegations of negligence, which may broaden the pharmaceutical manufacturer's potential exposure for injury caused by adulterated drugs. For example, desperate plaintiff's attorneys may claim that a drug manufacturer has reason to know that the drugs it sells to a company in a foreign country may become adulterated because they are not being properly refrigerated and stored.

These attorneys may further allege that the manufacturer has reason to know that U.S. consumers are traveling to this foreign country, purchasing those drugs, and reimporting them to the U.S. pursuant to the "personal use exception." A duty could be claimed on a "reasonably prudent drug manufacturer" to take steps to decrease the risk of harm those adulterated drugs pose to U.S. consumers, whether by additional warnings or other measures. Although it would be fundamentally unfair for consumers to seek to hold the manufacturer responsible for injuries caused by changes which occur to drugs after they leave the manufacturer's control, it is possible that the manufacturer's "superior" knowledge of an increased incidence of adulterated drugs could provide a basis for a court in a consumer-friendly jurisdiction to impose a duty. Further, whether claims against manufacturers are brought under a negligence theory or under a strict products liability theory or both, the manufacturer defending the claims must be prepared to expend substantial time and effort in tracking the drug's distribution through what may be a murky foreign system in order to acquire sufficient evidence to rebut any allegation that the drugs were adulterated when they left the manufacturer's control.

3. Inhibition of Research and Development

It has long been understood that the free market economy of the United States has provided the most productive climate in the world for innovation in the drug industry. Indeed, historically, the U.S. pharmaceutical manufacturers as a group are second to none in discovering and developing new drug products. It is no coincidence that a greater level of innovation is achieved in a country that does not restrict prices artificially, but instead allows manufacturers to generate sufficient revenue to invest in substantial research and development activities.

Reimportation of drugs from foreign countries (by some modification of the MEDS Act, and/or through the "personal use exception") has the potential to chill the very innovation that has made such drugs available in the first place. The reimportation of lower-priced drugs from foreign countries is not simply a reimportation of the drugs themselves but is also a reimportation of the price controls that are responsible for their lower cost. To permit reimportation of lower-priced drugs is to permit reimportation of economic factors that inhibit rather than encourage research and development activities.

At its simplest level, the issue can be viewed as a pure analysis of revenue and expenses. In order to meet its research and development budget, a pharmaceutical manufacturer must generate a certain amount of revenue based upon its sales. Given a fixed demand for a drug, if a greater percentage of consumers start to purchase the cheaper "reimported" version of the drug, then the reimportation of the drugs will lead to less revenue. Less revenue will then lead to diminished research and development expenditures. Under the circumstances, one would certainly expect that those who constantly bemoan the lack of sufficient research and development efforts by pharmaceutical manufacturers (a sentiment often expressed in the context of personal injury litigation) will line up along side pharmaceutical manufacturers in opposing reimportation because of its inhibitory impact on research and development activities.

On the other hand, when a pharmaceutical manufacturer experiences decreased revenue because a greater percentage of its domestic customers purchase reimported drugs at lower prices, the manufacturer is not compelled to decrease its research and development expenditures if it can find a way to recoup the diminished revenue. One way, of course, to recoup this diminished revenue is to raise domestic drug prices.

Pharmaceutical manufacturers are justified in pointing out that for every consumer who pays a dollar less for a reimported drug, another domestic consumer will have to pay a dollar more for the corresponding domestic drug in order for the manufacturer to continue necessary research and development efforts. To borrow former Secretary Shalala's words, any listing of the "flaws and loopholes" in the reimportation process must begin with an acknowledgement that reimportation will lead either to higher domestic drug prices or to decreased research and development activities on the part of pharmaceutical manufacturers. Of course, the volume of reimported drugs sold to U.S. consumers will directly impact the magnitude of the increase in prices/decrease in research and development, and to date, it is not clear that reimportation via the "personal use exception" has had a substantial impact on either result. Still, it is clear that both of these results in any magnitude could be harmful to the American public, and in particular to our senior citizens, who have the greatest reliance on prescription medicines.

4. Lack of Learned Intermediary

Under the traditional prescription drug distribution system, the physician who prescribes a drug to a consumer is warned of the drugs potential risks via FDA-approved package insert information. Restatement (Second) of Torts, section 402A, comments K, noted that prescription drugs are not defective or unreasonably dangerous when they were properly prepared and accompanied by adequate warnings. The pharmaceutical manufacturer derives protection from strict liability through the "learned intermediary" doctrine, which allows the manufacturer to discharge its duty to warn by providing warnings to the prescribing physician. The prescribing physician makes an assessment of

the risks and benefits of prescribing the drug and passes along the information he or she believes is pertinent to the consumer. The Restatement (Third) of Torts: Product Liability, Section 6(d)(1) continues to recognize the learned intermediary rule in traditional physician-patient prescription medication distribution. (See, comment b, "Subsection (d)(1) retains the 'learned intermediary' rule.")

Even before the reimportation issue became more prominent in the public consciousness, the protection of the learned intermediary doctrine was beginning to wane, with some courts recognizing exceptions in cases involving departures from the traditional drug distribution system, such as vaccines, oral contraceptives and the nicotine patch. Direct-to-consumer ("DTC") advertising also alters the traditional relationship among pharmaceutical manufacturer, the "learned intermediary" and the consumer, so that some courts have found an erosion of the protection of the learned intermediary doctrine. (See Berger, "A Tale of Six Implants; The Perez v Weith Laboratories Norplant case and the Applicability of the Learned Intermediary Doctrine to Direct-to-Consumer Drug Promotion" 55 food drug L.J., 525 (2000).)

The reimportation of prescription drugs through means of the "personal use exception" further changes the system of communicating drug information to the consumer. While certain drugs may require a prescription in the United States, many of these same drugs are available without a prescription in foreign countries. Therefore, there is a greater likelihood that there is no prescribing physician intermediary for these foreign-purchased drugs. Further, even if a prescription from a foreign physician is necessary to purchase a certain drug in a particular foreign country, the physician may

have a business relationship with a pharmacy that is designed to facilitate the prescription drug-purchasing transaction, such that the physician is operating less like a "learned intermediary" and more like a businessman. A language barrier between the physician and the consumer can further distance the reimportation transaction from the traditional drug distribution process, particularly if package inserts are not provided (or are in a foreign language). Finally, the foreign "learned intermediary" may prescribe the drug for an off-label use without being cognizant of a purchaser's medication history.

VI. LIMITING REIMPORTATION RISK

Having identified several key risks of reimportation, the question remains as to what to do about the identified issues surrounding reimportation. We provide the following suggestions to stimulate additional thought and discussion toward an effective reduction of the risks of reimportation.

1. **Rethinking reimportation legislation.** To help ensure the health and safety of the American public as to the quality of prescription medicines consumed within U.S. borders, Congress should rethink legislation condoning reimportation. To allow reimportation to occur in the face of the above-identified risks is to disregard a clear and present danger to the American public. Where recent estimates have been made by representatives of the World Health Organization testifying before Congress that 10% of the branded drugs found throughout the world are counterfeit, proponents of reimportation legislation must be made to understand that any claimed short-term savings

pales in comparison to the long-term health risks reimportation brings to American consumers.

2. **Codification of the "personal use exception."** As an additional safety measure, the FDA should revoke its non-codified "personal use exception" and properly enforce the reimportation prohibitions enacted by Congress. If the FDA, or our government representatives, believe that a limited "personal use exception" should be allowed, then this exception should be codified pursuant to the FDA's "notice and comment" rulemaking powers. In this way, Americans bringing prescriptions across U.S. borders will be guided by specific regulations and not the current thinking of a government agency.

3. **Immunity provisions.** If the prevailing thought of the American public and its representatives is to relax reimportation laws, then it is the authors' view that immunity provisions for pharmaceutical manufacturers should be made a part of any reimportation legislation. Immunity provisions would level the playing field as to claims in the U.S. stemming from injury to individuals who knowingly consume reimported drugs from areas outside the U.S. where safeguards may be lacking.

4. **Public Education Measures.** Given the likelihood of continued debate over lower cost drugs, and the continued viability of the "personal use exception," there is a current need for our government to provide better public awareness regarding the risks associated with reimportation. More and better dissemination of information should be made at our borders to further educate reimporting consumers as to the dangers identified in this paper. Placards and informative "brochures" at customs should be used to highlight drug reimportation safety risks.

An educational program would have a two-fold benefit. First, it would give the reimporting consumer information from a neutral source as to the risks associated with reimporting drugs from a foreign country. A reimporting consumer would then be informed/reminded of risk information so the consumer could determine whether he or she wished to accept the risks posed by reimportation. Secondly, pharmaceutical manufacturers would benefit from this educational program, as any subsequently injured consumer who reimports a drug would have been apprised of the risks associated with this reimportation. If this consumer chose to sue, his or her assumption of risk would be well established.

CONCLUSION

The reimportation of prescription medications from foreign countries that lack the safeguards of the American system of pharmaceutical production and distribution presents health and safety risks to the American public and to U.S. pharmaceutical manufacturers. An intelligent review of these risks shows that legislation and regulation allowing for reimportation is not in the best interests of the U.S. public or U.S. businesses. Steps should be taken by government and business leaders to promote better education and methods for alleviating these risks. Finally, if Congress is intent on passing legislation to help the American public obtain prescription medications, it should do so by broadening drug coverage programs, not by imperiling lives through reimportation.