

Prescription Drug Importation as a Policy Option to Lower the Cost of Medications in the U.S.

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Executive Summary

In 2004, four competing proposals to legalize prescription drug importation were introduced in Congress. Although none were passed, similar proposals have been reintroduced in 2005. The Medicare Modernization Act (MMA), enacted in 2003, created the U.S. Department of Health and Human Services (HHS) Task Force on Drug Importation and mandated that it report to Congress on the safety of drug importation and included a provision that would allow importation of drugs from Canada if the HHS Secretary certifies to Congress that such imports do not threaten the health and safety of the American public and do provide cost savings. However, the Secretary has not certified such a program.

As the debate continues at the federal level, several states have created programs in defiance of the U.S. Food and Drug Administration (FDA), steering Americans to the Web sites of Canadian and European pharmacies that they deem safe and reliable. In January 2004, the state of Vermont brought suit against the Bush administration for failing to write regulations for legal drug importation, and attorney generals from 18 states requested that the federal government immediately allow states to become licensed wholesalers or allow them to contract with licensed wholesalers to import medications from Canada.

In light of this recent activity, the American College of Physicians (ACP) feels it is necessary to further develop its position on prescription drug importation. A more comprehensive ACP position on this issue is needed for the College to respond to patients' needs in obtaining affordable prescription drugs. Furthermore, the College will be better prepared to respond to federal proposals, which are quickly gaining traction, and state actions, which are already under way. It is important that ACP continue to educate its members about the risks and benefits associated with drug imports, continue to review newly reported evidence related to risks and safety, and revise its position on the safety and effectiveness of drug importation as is necessary. This paper does not attempt to critique the pharmaceutical industry's pricing practices or dictate how the industry should be paid.

Background

Although the terms are used interchangeably, “importation” typically refers to drugs produced abroad and brought into the United States. “Reimportation” refers to drugs produced in the U.S. and exported for sale abroad, then later returned to the U.S. For purposes of this paper, the terms “reimportation” and “importation” are used interchangeably since the proposals currently before Congress do not distinguish between the terms in regard to the safeguards that would be required before the drugs could be brought back to the U.S.

Federal law strictly regulates the importation of pharmaceuticals through the Federal Food, Drug, and Cosmetic (FD&C) Act. Currently, the only types of legally imported drugs are 1) those that are manufactured in foreign FDA-inspected facilities and the subject of an FDA-approved drug application or 2) those that are U.S.-approved and manufactured in the United States, sent abroad, then re-imported to the U.S. by the manufacturer under proper controls and in compliance with FD&C Act requirements. All imported drugs are required to meet the same standards as domestic drugs and, thus, cannot be unapproved, misbranded, or adulterated. This prohibition extends to drugs that are foreign versions of U.S.-approved medications and drugs dispensed without a prescription (1).

In the 1980s, two separate policies emerged relating to the importation of prescription drugs amidst concerns over quality and safety:

- Commercial imports: The Prescription Drug Marketing Act of 1987 established today’s “closed system” of distribution, which prohibits anyone other than the original manufacturer from importing an approved drug that was manufactured in the U.S. and then shipped overseas.
- Personal use imports: The FDA exercises its enforcement discretion under certain circumstances and does not stop individuals with serious conditions from bringing treatments into the U.S. that are legally available in foreign countries but are not approved in the U.S. (1). This lenient “personal use” policy, which permits individuals to import a 90-day supply of non-FDA-approved prescription drugs, was developed out of concern that certain AIDS treatments were not available in the U.S. (2). The policy was never intended to be a way for patients to purchase lower-priced drugs in foreign countries, although it has resulted in such.

In 1992, the Prescription Drug User Fee Act was passed to speed up the lengthy review process of new drug applications. As new drugs began to enter the market quickly, expenditures for drugs in the U.S. began to climb, in part as a result of greater use of newer treatments, which are often more costly than older medicines. Meanwhile, drug prices abroad remained low as a result of centralized negotiations. In response to mounting political pressures, concerns over rising drug costs, and growing international price differences, Congress passed the Medicine Equity and Drug Safety Act of 2000 (the MEDS Act), which created a 5-year program to allow imports by pharmacists and drug wholesalers, although drugs could be imported only from specific countries. In order for this to take place, the Secretary of HHS had to certify that imported drugs posed no additional risk to the public’s health and safety and resulted in a significant reduction in cost. However, neither the Clinton nor the Bush administration certified the safety of importation, thus preventing importation by wholesalers and pharmacists.

In 2003, Congress passed the Medicare Modernization Act (MMA), which included an importation provision similar to the MEDS Act. The provision provides authority for pharmacists and wholesalers to import certain drugs from Canada, subject to certain conditions. It also directs the Secretary of HHS to grant waivers to permit importation of a 90-day supply of any FDA-approved prescription drug from a licensed Canadian pharmacy for personal use. The MMA provision differs from the MEDS Act in that it 1) directs the Secretary to allow imports from Canada only (the MEDS Act had allowed imports from a specific list of industrialized countries, including Canada); 2) codifies the discretion in enforcement that the FDA has exercised to allow the “personal use” imports of prescription drugs; 3) prohibits manufacturers from entering into agreements to prevent the sale or distribution of imported products; and 4) includes a mechanism, based on evidence, by which the Secretary can terminate the import program (2). However, similar to the MEDS Act, for any of these provisions to take effect, the Secretary of HHS must certify to Congress that such imports do not threaten the health and safety of the American public and do provide cost savings.

Scope

Imported drugs continue to enter the U.S. from all corners of the globe, from both developed and developing countries. In 2003, Americans imported \$1.4 billion in prescription drugs. Of this total, an estimated two million Americans purchased about 12 million prescription drug products with a value of approximately \$700 million from Canada (1).

Current Congressional Action

Since 2003, legislation has been introduced to accelerate the legalization of drug importation. In the 108th Congress, four major proposals were introduced to legalize the importation of prescription drugs. The House passed one bill, but Senate leadership blocked efforts to hold hearings and floor action on a similar measure before the end of the session. In the 109th Congress, three viable drug importation proposals have been introduced, all of which are similar to the proposals considered in the previous Congress. The three bills differ in the number of countries from which importation would be permitted, the time at which importation could begin following enactment, and the extent of measures to ensure safety.

Of these four proposals, the Pharmaceutical Market Access and Drug Safety Act of 2005 (S 334/HR 700), introduced by Senators Dorgan (D-ND) and Snowe (R-ME) in the Senate and Representatives Emerson (R-MO) and Brown (D-OH) in the House, is a leading vehicle for legislative action. Under the bill, pharmacies and wholesalers could import drugs from FDA-approved pharmacies in 25 countries—including Canada, European Union nations, Australia, New Zealand, Japan, and Switzerland—within 1 year of the bill’s enactment. Individuals could also buy and import as much as a 90-day supply of prescription drugs for personal use from registered Canadian pharmacies via mail-order or the Internet. The Dorgan–Snowe bill includes a range of safety features, including:

- Requiring pharmacies and drug wholesalers to register with the FDA and be subject to frequent, random inspections.
- Limiting the number of licensed importers for the first 2 years.

- Allowing only the importation of FDA-approved medicines with a chain of custody that can be traced back to an FDA-inspected manufacturing plant.
- Requiring that the FDA review notices of foreign versions of the top 100 selling domestic FDA-approved drugs to determine whether they are the same as their U.S. counterparts.
- Allowing the use of anti-counterfeiting technology to identify safe, legal imported medicines.
- Requiring pharmacies and wholesalers to pay fees of as much as 1% of the price of the medications to fund the cost of additional federal inspectors and customs agents. These entities also would have to pay registration fees.
- Requiring frequent, random FDA inspection of Canadian pharmacies, including those marketing their drugs via the Internet.
- Requiring that imported drugs be labeled in English and packed in tamper-proof packages.
- Establishing standards for Internet pharmacies.

The Dorgan–Snowe bill also includes a non-discrimination provision that would make it illegal for drug manufacturers to shut down the supply of prescription drugs to certain pharmacists and wholesalers, as they are currently doing in Canada. In the previous Congress, the bill had bipartisan support, the backing of 24 organizations, including American Association of Retired Persons (AARP) and American Federation of Labor–Congress of Industrial Organizations (AFL-CIO), and the support of a former FDA commissioner.

The other proposals currently in Congress differ in their safety requirements. For instance, the Pharmaceutical Market Access Act of 2005 (S 109/HR 328), introduced by Senator Vitter (R-LA) and Representative Gutknecht (R-MN), requires less frequent FDA inspections of importers and exporters than the Dorgan–Snowe bill. It does not limit importation to FDA-approved products or require verification of the chain of custody. Similarly, the Safe IMPORT Act of 2005 (S 184/HR 753), introduced by Senator Gregg (R-NH) and Representative Bradley (R-NH), does not require inspections of commercial drug shipments, does not authorize inspection of all entities in the chain of custody, does not require FDA inspection of Internet pharmacies, and only permits inspection of records if FDA has “reason to believe” that an imported drug “presents a risk to public health.” The Safe IMPORT Act also does limit importation to FDA-approved products and would proceed more cautiously than the Dorgan–Snowe bill by limiting drug importation only to Canada for the first 3 years. However, it does not include an analogous, non-discrimination provision to prevent drug companies from shutting off supplies to pharmacies that sell to Americans.

Legislation aimed at more specific aspects of importation has also been introduced in Congress this year. For example, the Ryan Haight Internet Pharmacy Consumer Protection Act of 2005 (S 399/HR 840), sponsored by Senators Coleman (R-MN) and Feinstein (D-CA) and Representatives Davis (R-VA) and Waxman (D-CA), would strengthen standards governing Internet pharmacies. It would prohibit Internet pharmacies from distributing drugs to consumers with a prescription solely on the basis of an online questionnaire and would give state attorneys general the ability to shut down rogue Web sites nationwide, rather than just in their individual jurisdictions. The Safe Online Drug Act of 2005 (HR 1808), introduced by Representatives Walden (R-OR) and Davis (D-FL), would create a uniform certification standard to ensure that

all U.S.-based Internet pharmacies meet rigorous FDA standards and adhere to state regulations for operating a pharmacy. At present, safety standards for Internet pharmacies are voluntary.

MMA Study

The MMA mandated that a task force be formed to report to Congress on the safety of drug importation. The HHS Task Force on Drug Importation, appointed by HHS Secretary Thompson, conducted six “listening sessions” where members heard from consumer advocates, health care purchasers, providers, health care industry representatives, international stakeholders, and the public.

In December 2004, the HHS Task Force on Drug Importation issued a final report, concluding that drug importation would be costly to implement; could slow research and development of new drugs; and, if not restricted to Canada, could be dangerous to consumers (3). The report also concluded that importation would provide little savings overall, claiming that while wholesalers—the middlemen in drug importation—stand to gain the most from legalized drug importation, consumer savings would be modest after taking into account the cost of liability suits.

In a letter accompanying the report, the Secretaries of HHS and the U.S. Department of Commerce outlined the conditions under which the administration would support drug importation. The letter stated that commercial drug importation should involve high-volume, high-cost prescription drugs from a country with comparable drug safety standards, noting that Canada is the only country from which importation should be considered at this point. According to the letter, only commercial importation from licensed foreign wholesalers should be permitted, while personal importation through the mail should be excluded. Other safeguards, such as labeling requirements and inspection procedures, also were outlined in the letter (4).

Recent State Action

As constituents become increasingly frustrated with the high cost of drugs and with Congressional inaction on the issue of importation, more and more pressure is being placed on state and local officials. In 2004, attorney generals from 18 states sent a letter requesting that the Secretary of HHS immediately allow states to become licensed wholesalers or allow them to contract with licensed wholesalers to import medications from Canada. Throughout the year, governors of Iowa, Illinois, Minnesota, New Hampshire, and Wisconsin approached the administration seeking, at minimum, a waiver to conduct pilot programs to test ways to safely import medications. The FDA has remained steadfast in its refusal to consider such arrangements, despite an agreement from the states to allow the FDA to shut down a pilot if any violations were found. In August 2004, Vermont state officials went so far as to file suit against the FDA when the agency denied the state’s request for a waiver to authorize a drug importation pilot project.

The lack of consensus in Congress to address importation has pushed state and municipalities to enact their own importation programs. In 2004, 28 states and the District of Columbia considered drug importation measures (5). Minnesota, which currently has the largest government-sponsored program, launched the first Web site in the nation—RxConnect.com—linking residents to Canadian mail-order pharmacies that meet state established standards of safety. Illinois, Wisconsin, Missouri, Kansas, and Vermont have joined together

under the I-SaveRx.net program, under which states contract with a Canadian pharmacy benefit manager that connects residents with a clearinghouse of 45 pharmacies and prescription drug wholesalers in Canada, the United Kingdom, and Ireland. Health insurance plans are required to provide coverage for drugs purchased through the program on the same terms and conditions as prescription drugs purchased in the U.S. About 1,900 residents enrolled in the program in the first 3 months (6). The state of New Hampshire introduced a Web site offering residents information on ordering prescription drugs from Canadian pharmacies, while Boston's mayor launched a drug importation pilot program for 14,000 city employees and retirees. Various other locales have launched similar programs, including Springfield, Massachusetts; Montgomery, Alabama; and Montgomery County, Maryland.

In January 2005, Rhode Island's Department of Health was the first in the nation to file regulations to allow residents to purchase prescription drugs from Canada. The regulations give the Rhode Island Board of Pharmacy the authority to license Canadian pharmacies in the same manner that it licenses other out-of-state mail-order pharmacies (5). The pharmacies must be licensed by regulators where they are based, and Rhode Island regulators retain the right to inspect the Canadian locations if necessary. The regulations also specify minimum staffing and safety requirements at the pharmacies. Residents can fill prescriptions from the Canadian pharmacies by using the Internet, telephone, or other methods and receive the medications through the mail or a private delivery service (7).

The FDA has, for the most part, refrained from taking formal action against states and municipalities that have instituted such programs. Instead, the agency has sent letters to those entities advising them of the safety risks associated with importing medicines. The FDA has also warned that such programs may violate federal law and that states could face tort liability suits and charges of assisting in criminal activity if individuals suffer injury from these drugs.

In a few cases, however, the federal government has acted with tighter enforcement. In 2003, the U.S. Department of Justice filed a lawsuit on behalf of the FDA against two sister companies, Rx Depot Canada LLC and Rx Depot Inc., that enabled U.S. residents to purchase lower-cost prescription drugs from Canada. The government claimed that the storefront pharmacy violated a federal law that allows only prescription drug manufacturers to import medications into the U.S. In December 2004, the FDA obtained an injunction prohibiting the company from importing prescription drugs and requiring the company to tell its customers that its drug import business violates the law (8). The FDA has also threatened to take the state of Illinois to court for initiating its drug import program, which is increasingly gaining the support and participation of other states.

In response to growing concerns about the adequacy of supply in Canada, given rapidly growing and illegal trade through Canadian Internet pharmacies, many pharmaceutical companies established supply integrity programs. In January 2005, Merck & Co., the second largest U.S. drug maker, began shutting off sales to Canadian pharmacies exporting drugs to American patients. Merck became the fourth drug maker to take such a step, joining Pfizer Inc., AstraZeneca PLC, and Wyeth. In reaction, consumer groups have filed lawsuits against these pharmaceutical companies, claiming that they are violating antitrust and consumer-protection laws by reducing supplies to Canadian pharmacies that sell medicines to Americans. Minnesota's governor is now considering importation agreements with countries in Europe and elsewhere because pharmaceutical companies threatened to end supplies of their products to Canadian online pharmacies that sell to Minnesota residents.

Response of Canadian Officials

In June 2005, the Canadian Health Minister announced that he plans to introduce legislation that would allow for the temporary ban of bulk exports when supplies are running low at home. He also intends to establish a drug supply network within the federal ministry Health Canada and work with provinces and pharmaceutical companies to provide more comprehensive data on Canada's prescription drug supply. The Canadian Health Minister has continually warned that importation by the U.S. is cutting into Canada's ability to adequately supply medications to its citizens. Although no shortage currently exists, Canadian officials are concerned that if importation legislation is passed, Americans will flock to Canada and disrupt the supply chain in this much smaller nation. The Canadian Health Minister previously suggested establishing a list of prescriptions on which the Canadian government can restrict sales in the event of a shortage. He also has proposed a crackdown on online pharmacies that sell prescription drugs to U.S. residents and proposed restrictions against Canadian physicians co-signing prescriptions for U.S. residents who are not present and have not been examined. Although there is no law against signing foreign prescriptions without seeing the patients, physician regulatory boards in Canada have ethics rules against the practice (9).

Advocacy groups for U.S. seniors have begun to examine proposals to purchase prescription drugs from European and Asian nations because of concerns that the Canadian government might block the sale of lower-cost medications to the U.S. While supporters maintain that the prescription drug regulatory systems of European nations are as safe as those in the U.S., others cite the dangers of the European system, which operates under "parallel trade," where any European country can import drugs from any other European country.

Private Sector

As drug importation proposals are debated, the private sector continues to evaluate and develop strategies to ensure the safe distribution of prescription drugs. In 2005, the National Association of Boards of Pharmacy (NABP) launched the Verified Accredited Wholesale Distributors (VAWD) program to accredit wholesale drug distributors. The program, which includes inspections paid for by the wholesaler, is designed to protect the public by preventing counterfeit drugs from entering the U.S. drug supply. The VAWD accreditation assures stakeholders that wholesaler distributors are legitimate, are qualified for state licensure, and are using security and best practices for safely distributing prescription drugs. The program is similar to the NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program, which developed a certification process for Internet pharmacies in 1999. To be VIPPS-certified, a pharmacy must comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals. Pharmacies must also comply with VIPPS criteria, including patient rights to privacy, authentication and security of prescription orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients and pharmacists.

The American Medical Association (AMA) recently endorsed the importation of prescription drugs by wholesalers and pharmacies, provided that the medications are FDA-approved and are subject to reliable electronic tracking and that Congress provides the FDA with the resources and authority to ensure that the supply is reliable. The AMA continues to oppose individual importation through Internet pharmacies until safety can be guaranteed.

Public Opinion

A recent Kaiser Family Foundation survey found that 73% of Americans think Congress should change the law to allow prescription drug importation. Only 21% oppose such measures. Sixty-nine percent said legalizing the practice would make medicines more affordable without sacrificing safety (10). A separate survey found that public support for drug importation decreased significantly when respondents were asked about specific countries. Respondents were far less likely to support importing medicines from European countries, such as Greece, Portugal, and Spain (40%); European Union members, such as Estonia, Latvia, and Malta (31%); or Asian countries, such as Japan (42%) than they were medicines from Canada (69%) (11).

Argument for Importation

High Cost of Drugs

Both proponents and opponents of importation have stated that the larger problem at hand is the lack of affordability of prescription drugs. The importation of drugs is one of many strategies to reduce drug costs. It is well documented that American consumers, particularly the elderly and uninsured, often pay more for prescription drugs than do citizens in other countries. Americans pay up to an estimated five times more to fill their prescriptions than consumers in other countries. American seniors alone will spend \$1.8 trillion on pharmaceuticals over the next 10 years (12).

Critics of the pharmaceutical industry cite that drug companies enjoy higher profits than any other industry year after year. In 2002, for example, the top 10 drug companies in the United States had a median profit margin of 17%, compared with only 3.1% for all the other industries on the *Fortune* 500 list (13).

Importation would not only give Americans access to more affordable prescription drugs but would also increase competition among pharmaceutical companies, which could help drive down the prices of prescription drugs produced in the U.S. An open pharmaceutical market could save American consumers at least \$38 billion each year (14).

Achieving Safety

Many prescription drugs that are commonly used by Americans are already being manufactured abroad. About four in 10 prescription drugs now sold in the U.S. are manufactured abroad, including most cholesterol-lowering medications that are manufactured in Ireland, such as Lipitor (Pfizer Inc.). According to William Hubbard, associate commissioner of the FDA, the agency inspects the part of the Irish plant that makes the pills sold in the U.S. (15).

Although a system has been created to ensure safety, these inspections do not always take place due to a lack of resources. The FDA is supposed to inspect each foreign drug manufacturer at least every other year, but with only about \$50 million each year to complete all drug inspections, both domestic and foreign, the agency finds it impossible to fulfill this obligation (15).

Supporters, therefore, continue to advocate for strengthening and expanding the current regulatory system, including inspections of foreign production plants, licensing of wholesale importers, tracking of shipments from factories to pharmacies, and the creation of an FDA Web site that lists approved pharmacies that could supply U.S. residents with safe prescription drugs from other nations.

With an estimated two million Americans already importing prescription drugs without any safety mechanisms in place, proponents of importation continue to urge Congress to act to ensure the safety of these individuals.

State Support

Various state officials, including those from Minnesota, Iowa, Vermont, and North Dakota, have testified in support of importation. At a February 2005 hearing held by the Senate Health, Education, Labor, and Pensions Committee (HELP), Minnesota Governor Pawlenty noted that safety concerns have not been a problem for his state's drug importation program, RxConnect.com. Walgreens and CVS Pharmacy, the top two pharmacy chains in the U.S., have also expressed support for importation on the condition that a safe channel be established.

Canada-Only Approach

Still others defend Canada-only importation proposals by attesting to the security of the Canadian system. The President of Ontario-based CanadaPharm, a mail-order pharmacy that supplies Americans with prescription drugs from Canada, has noted that Canada's pharmaceutical approval and regulatory process, regulated through the Therapeutic Products Directorate, is "equally as rigorous" as that of the FDA. He also pointed out that there is more opportunity inside the U.S. than in Canada for "illicit drugs entering the drug distribution system." Only five prescription drug wholesalers exist in Canada, in contrast to several hundred in the U.S. Furthermore, medications are dispensed to pharmacies in manufacturer-sealed packages, unlike in the U.S., where wholesalers may repackage them (16).

Argument against Importation

Safety Concerns

The most vocal argument against prescription drug importation centers on safety. Opponents fear that foreign drugs may be improperly labeled, stored, and shipped. Concerns have also been raised about the substitution of similar but not "therapeutically equivalent" products and recall management. Most serious of all, however, is the increased potential for exploitation by counterfeiters, narcotics traffickers, organized criminals, and terrorists, leading to an increase in altered and counterfeit treatments entering the U.S. and increased risk for bioterrorism. The FDA, the World Health Organization, and pharmaceutical companies report that counterfeit cases are on the rise. Other studies have documented links between counterfeit products and terrorist organizations, which engage in such activity to finance their operations (5).

In 2003, the FDA and the U.S. Customs and Border Protection conducted a series of spot examinations of mail shipments of foreign drugs entering the U.S. Of the 1,153 imported drug products examined, the overwhelming majority of the drugs (88%) were found to be in violation of U.S. federal pharmaceutical safety or efficacy standards. These drugs came from many countries, including Canada, India, Thailand, and the Philippines. The potentially hazardous medicines found included drugs different from those approved by the FDA, inadequately labeled

or packaged drugs, drugs withdrawn from the market, animal drugs that are not approved for human use, drugs with dangerous interactions, drugs that carry risks requiring initial screening and/or periodic patient monitoring, and controlled substances (17).

On 20 May 2004, the Senate HELP Committee held a hearing where FDA Associate Commissioners Hubbard and Taylor warned of counterfeit medications from India, Indonesia, and Pakistan, as well as prescription drugs that have the same chemical analysis as others but do not properly dissolve in the bloodstream.

Finally, the Government Accountability Office (GAO) reported in July 2004 that the FDA and U.S. Customs and Border Protection officials were concerned that the volume of imported, adulterated, misbranded, or unapproved prescription drugs is large and increasing. The GAO concluded that federal agencies cannot assure American consumers that prescription drugs purchased from international distributors are safe, effective, or high-quality. Another recent GAO report on drugs purchased from the Internet echoed these concerns.

The Secretaries of HHS for the Clinton and Bush administrations, the FDA, 11 former FDA Commissioners, the U.S. Customs Service, and the Drug Enforcement Administration have all voiced concerns over drug importation.

Weaknesses in the Current System

Those concerned with safety often point to weaknesses in the current system, which must be corrected before drug importation can be made legal. Lack of resources is a significant contributor to security lapses. The FDA currently has only about 100 investigators nationwide to handle the approximately 10 million parcels coming into the U.S. annually. At the U.S. Post Office Airport Mail Facility at JFK Airport, for example, only 1%–2% of the 40,000 packages received daily are inspected. As a result, non-FDA-approved medications are entering the U.S. at a rapid pace. Random inspections conducted by the FDA at several mail facilities revealed that 86%–88% of the packages examined contained non-FDA-approved drugs (5).

The current system also lacks a uniform mechanism to track medicine from the point of manufacture to the point of sale, such as a chain of custody or “pedigree,” as well as uniform interstate standards to regulate wholesalers and distributors. Furthermore, Internet pharmacies are not currently regulated, making it difficult to ensure product quality and origin or to ensure that a prescription is required or a physician is employed (5).

The FDA has been particularly vulnerable to criticism following its failure to inspect often enough the long-troubled British vaccine plant owned by Chiron, which the U.S. had counted on for half of its flu vaccine supply. The plant’s entire vaccine supply was impounded last year after British regulators discovered serious problems, which were later confirmed by the FDA.

The President’s fiscal year 2006 budget proposal would reduce funds for almost all FDA inspection programs, such as those that review overseas plants that make prescription drugs bound for the U.S. If Congress approves these provisions, the number of foreign drug plant inspections would drop 5.8% compared with estimated 2005 inspections. The only increases are an expansion of a network of labs to analyze food for bioterror agents and increasing staffing in the office that monitors the safety of prescription drugs once they hit the market (18).

High Cost of Ensuring Safety and Uncertainty of Savings for Consumers

A 2004 report by HHS found that assuring the safety of imported medications would be so costly—hundreds of millions of dollars—that consumers would see a price break of only about 1%. A 2004 analysis by the Congressional Budget Office (CBO) similarly concluded that the savings from such a program are expected to be small, especially in a Canada-only approach (19). Critics also fear that middlemen, such as wholesalers and Internet pharmacies, will reap most or all of the savings from importing lower-priced pharmaceuticals, rather than pass the savings on to consumers.

Impact on Research and Development

The U.S. continues to lead the world in biotechnology innovation because our national policies foster innovation. Unlike nations that impose price controls to ensure prescription drug affordability, pharmaceutical companies in the U.S. are free to sell at whatever price they choose. According to manufacturers, the high price of drugs in the U.S. is largely a result of the pharmaceutical industry being a high-risk business that requires substantial investments in research and development. Last year, member companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) spent more than \$33 billion on research and development. In contrast, all pharmaceutical companies, including those that are not members of PhRMA, spent \$21 billion on total promotion and marketing combined (20).

Pharmaceutical companies argue that if importation were legalized, their incentive to invest in research and development would be reduced. The final report of the HHS Task Force concluded that legalizing imports would cut drug companies' profits, which pay for research and development, resulting in three or four fewer new drugs being approved each year (3). Another study estimated that if importation was approved, national research and development spending by pharmaceutical and biotechnology firms would plummet by \$14.8 billion over the next 12 years and 262 life-saving drugs would be abandoned for economic reasons (21). Importation could also erode incentives for providing low-cost generics.

Disruptions in the Canadian Supply

Still others warn of the adverse effect importation may have on the Canadian supply. Canada, which fills about 300 million prescriptions annually, lacks the infrastructure and supply to provide for Americans, who fill 3.1 billion prescriptions annually, in addition to its own residents (5). Since Canada's population is just a fraction of the size of the U.S., even a small portion of U.S. patients ordering medications from across the border could overwhelm current supply and distribution systems. The end result would be higher prices and limited supplies for Canadian patients. In the event that Canada faces a prescription drug shortage, the nation could declare an emergency and remove patent rights for medications. In a worst-case scenario, the Canadian government could ban all prescription drug exports to the U.S.

Liability Concerns

Importation also raises concerns about liability in the event that a patient is harmed by an imported medicine. American pharmaceutical companies, pharmacies, pharmacists, hospitals, and physicians can all be sued and held liable for prescribing and dispensing imported medications that injure patients. Many complicated issues related to liability have yet to be resolved, including who would be at fault (i.e., importer, prescribing physician, dispensing pharmacist, or manufacturer), jurisdiction (e.g., suits might require going to foreign courts), and the role of the patient (e.g., determining patient fault when he or she is aware of the source of the product).

Alternative Ways for Consumers to Access Lower-Cost Drugs

Significant progress has been made over the last few years in both the public and private sector to improve patients' access to affordable medications. The MMA of 2003 includes a comprehensive outpatient prescription drug benefit that will be available to all Medicare beneficiaries beginning on 1 January 2006. This benefit will provide savings on medications for Medicare beneficiaries, with the most assistance being provided to low-income individuals and those with very high drug expenditures. Forty million Medicare beneficiaries, including approximately 12 million without any coverage today, will be able to access affordable and safe medications with protection against high out-of-pocket costs. Approximately 11 million low-income elderly and disabled individuals will pay only minimal co-payments for this coverage.

In addition to the new Medicare benefit, the pharmaceutical industry has taken steps to improve access to medicines for the uninsured. Eli Lilly created the Lilly Cares program, which offers free medication, through physicians, to patients who are otherwise unable to obtain their products. Eli Lilly also developed the LillyAnswers program to help address concerns about growing medical expenses for Medicare recipients without prescription drug coverage. For eligible seniors, LillyAnswers provides a 30-day supply of any Lilly retail drug for a flat \$12 fee. Pfizer's Helpful Answers Initiative includes the Pfizer Pfriends program, through which low-income, uninsured families can buy medicines at prices similar to those paid by large purchasers, as well as the Connection to Care program, through which families making \$31,000 or less per year can receive free Pfizer medicines from their physicians' offices. Novartis and nine other pharmaceutical companies recently launched the Together Rx Access card, a free program, which provides low-income uninsured individuals with savings of approximately 25%–40% on a wide range of prescription products. Finally, the Partnership for Prescription Assistance (PPA) is another collaborative effort among pharmaceutical companies, health care providers, patient advocacy organizations, and community groups to help qualifying patients who lack prescription coverage get the medicines they need. The PPA (www.pparx.org) offers a single point of access to more than 275 public and private patient assistance programs, including more than 150 programs offered by pharmaceutical companies.

Where We Stand

In January 2005, the College's Board of Regents (BOR) voted to modify the College's policy on prescription drug importation. An ACP policy previously "oppose[d] reimportation until safety concerns raised by HHS and the FDA were resolved." The new policy states that "ACP supports legislative and/or regulatory measures to develop a process to ascertain and certify the safety of reimported prescription drugs." The position was amended to allow the College to be more responsive to patients suffering from the high cost of prescription drugs without criticizing the pharmaceutical industry's pricing practices or dictating how the industry should be paid.

Although this modified policy allows the College to respond more proactively, its lack of specificity makes it an inadequate tool to evaluate and respond to quickly evolving importation proposals and actions at the federal and state level. The following recommendations, based on the arguments presented in this paper, will better guide the College in evaluating proposals on the issue of prescription drug importation:

Recommendation 1: Action is needed, including consideration of drug importation, to reduce the high cost of prescription drugs in the United States. However, assuring high quality and patient safety must remain the top priority of any cost control program.

Recommendation 2: Before legalizing the importation of prescription drugs, Congress should:

- Permit state pilot programs to test the safe implementation of prescription drug importation programs. Trials could initially be aimed at individuals without drug coverage. The results of such pilots should serve as a model for the federal government and individual states.
- Create an independent FDA oversight board to handle drug safety issues, including those related to prescription drug importation, and to communicate more effectively with patients and physicians about the risks and benefits of such medications.
- Study and report on the effectiveness of promising new and emerging anti-counterfeiting technologies, such as radio frequency chips to track drug shipments. Nevertheless, it should be recognized that widespread adoption of authentication technologies is a daunting task that could raise the cost of imported drugs, thereby reducing any expected savings from importation.
- Urge the expansion of accreditation programs. In particular, ACP urges the NABP to consider applying its Internet pharmacy accreditation program on an international level to help consumers identify legitimate Internet pharmacies.
- Enhance resources of the FDA to inspect facilities manufacturing prescription drugs for export to the U.S. and enhance resources of the FDA, the U.S. Customs Service, law enforcement agencies, and other federal agencies involved in assuring that products that are illegal, are counterfeit, or do not meet U.S. safety and quality standards are not allowed into the U.S.

Recommendation 3: ACP believes that any drug importation system that Congress approves should:

- Be a closed system, in which participating pharmacies and Internet sites must meet FDA standards;
- Have a tightly controlled and documented supply chain;
- Not include controlled substances, biologics, or products that are infused/injected or products that are photoreactive or have strict temperature requirements;
- Be limited to countries that meet U.S. standards to assure high quality and patient safety of imported drugs;
- Include adequate resources for inspections of facilities and enforcement of U.S. requirements; and
- Require that only prescriptions written by a U.S.-licensed physician with an established professional relationship with the patient be accepted for importation.

Recommendation 4: Prescription drug importation is not a long-term solution to the high cost of prescription drugs, which is having a detrimental effect on Americans' access to life-saving therapies. ACP urges the federal government to take immediate action to improve access to pharmaceuticals by:

- Assuring there are sufficient incentives for pharmaceutical research and development;
- Encouraging increased competition among brand-name manufacturers;
- Speeding the approval and encouraging the use of generic drugs;
- Negotiating volume discounts on prescription drug prices and pursuing prescription drug bulk purchasing agreements under the Medicare program;
- Expanding the availability of public and private sector health insurance that includes coverage for prescription drugs;
- Encouraging pharmaceutical manufacturers to expand their patient assistance and drug discount programs and increase patient education for these programs;
- Protecting state pharmaceutical programs that may be impacted by the new Medicare law;
- Reviewing recent increases in the cost of pharmaceuticals;
- Studying the effectiveness of prescription drug substitutes, such as lower-cost, therapeutically equivalent medications;
- Encouraging and helping to implement disease management programs;
- Encouraging the use of evidence-based medicine; and
- Considering limits on direct-to-consumer drug advertising.

ACP should work with its members to carry out those reforms of which it is capable.

Glossary

AMA: American Medical Association.

BOR: Board of Regents—manages the business and affairs of ACP. It is the main policy-making body of the College.

CBO: Congressional Budget Office—a supportive agency of Congress that provides nonpartisan analyses needed for economic and budget decisions, as well as information and estimates required for the Congressional budget process.

CMS: Centers for Medicare & Medicaid Services.

FDA: U.S. Food and Drug Administration.

FD&C Act: Federal Food, Drug, and Cosmetic Act—federal law that, among other things, strictly regulates the importation of pharmaceuticals.

GAO: Government Accountability Office (formerly the Government Accounting Office)—an independent and nonpartisan agency that provides Congress and executive agencies with studies of programs and expenditures of the federal government. The GAO is commonly known as the investigative arm of Congress, since it evaluates federal programs, audits federal expenditures, and recommends ways to make government more effective.

HELP: Senate Health, Education, Labor, and Pensions Committee.

HHS: U.S. Department of Health and Human Services.

Importation: Typically refers to drugs produced abroad and brought into the U.S.

MEDS Act: Medicine Equity and Drug Safety Act of 2000—bill that would have allowed for the importation of FDA-approved pharmaceuticals only if the Secretary of HHS first certified that such importation would not pose additional health risks to the American public and would create significant cost savings. Both the Clinton and Bush administrations determined that HHS could not implement the importation changes because neither the safety nor the cost-effectiveness of the MEDS Act could be ensured.

MMA: Medicare Modernization Act of 2003.

NABP: National Association of Boards of Pharmacy—professional association that represents the state boards of pharmacy in all 50 states, the District of Columbia, Guam, Puerto Rico, the Virgin Islands, New Zealand, eight Canadian Provinces, two Australian states, and South Africa.

PhRMA: Pharmaceutical Research and Manufacturers of America—represents the country's leading pharmaceutical research and biotechnology companies.

Reimportation: Refers to drugs produced in the U.S. and exported for sale abroad, then later returned to the U.S.

VAWD program: Verified Accredited Wholesale Distributors program—launched by the NABP in 2005 to accredit wholesale drug distributors. Accreditation by the VAWD helps assure stakeholders that wholesaler distributors are legitimate, are qualified for state licensure, and are using security and best practices for safely distributing prescription drugs.

VIPPS program: NABP's Verified Internet Pharmacy Practice Sites—a certification process for Internet pharmacies developed by NABP in 1999. To be VIPPS-certified, a pharmacy must comply with VIPPS criteria, as well as comply with the licensing and inspection requirements of their state and each state to which they dispense pharmaceuticals.

References

1. Statement of Dr. Richard Carmona. Hearing on Drug Importation: The Realities of Safety and Security, Committee on Health, Education, Labor, and Pensions, U.S. Senate. 16 February 2005. Accessed at http://help.senate.gov/testimony/t190_tes.html on 19 April 2005.
2. Thaul S, Vogt D. Importation of Prescription Drugs Provisions in P.L.108-173, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Congressional Research Service. 12 March 2004. Accessed at www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL32271.pdf on 19 April 2005.
3. Report on Prescription Drug Importation, HHS Importation Task Force, U.S. Department of Health and Human Services. December 2004. Accessed at www.hhs.gov/importtaskforce/Report1220.pdf on 8 July 2005.
4. Letter from Secretary of the Department of Health and Human Services, Tommy Thompson and Secretary of Commerce Donald Evans to Senate Majority Leader William Frist. 21 December 2004. Accessed at www.hhs.gov/importTaskForce/Frist.pdf on 19 April 2005.
5. Examination and Assessment of Prescription Drug Importation from Foreign Sources to the United States, Giuliani Partners, LLC. April 2005. Accessed at www.phrma.org/publications/policy/admin/2005-04-11.1162.pdf on 19 April 2005.
6. Lannan M. Fewer than 2,000 People Have Used Program to Import Prescriptions. Chicago Sun-Times. 20 December 2004. Accessed at www.suntimes.com/output/health/cst-nws-drug20.html on 19 April 2005.
7. Armstrong D. Rhode Island Plans to License Canadian-Based Pharmacies. Wall Street Journal. 3 January 2005.
8. Court Halts Illegal Importation of Prescription Drugs. FDA News. 27 December 2004. Accessed at www.fda.gov/bbs/topics/ANSWERS/2004/ANS01337.html on 19 April 2005.
9. Higgins M. HHS Chief Tackles Drug-Imports Issue. Washington Times. 18 March 2005.
10. Finkelstein J. Public Support Fuels Latest Reimportation Push in Congress. AMNews. 21 February 2005. Accessed at www.ama-assn.org/amednews/2005/02/21/gvsb0221.htm on 19 April 2005.
11. Most Americans Don't Favor Drug Imports from Non-Canadian Countries. The Polling Company. 9 March 2005. Accessed at www.pollingcompany.com/News.asp?FormMode=ViewReleases&ID=109 on 7 July 2005.
12. Crippen D. Projections of Medicare and Prescription Drug Spending: 2003-2012. Congressional Budget Office. 7 March 2003. Accessed at www.cbo.gov/showdoc.cfm?index=3304&sequence=0 on 19 April 2005.
13. Pattison N, Warren L. 2002 Drug Industry Profits: Hefty Pharmaceutical Company Margins Dwarf Other Industries. Public Citizen Congress Watch. June 2003. Accessed at www.citizen.org/documents/Pharma_Report.pdf on 20 April 2005.
14. Statement of U.S. Senator Byron L. Dorgan. Hearing on Comparative Pricing of Prescription Drugs Sold in the U.S. and Canada and the Effects on U.S. Consumers, Subcommittee on Consumer Affairs, Foreign Commerce and Tourism, U.S. Senate. 5 September 2001. Accessed at <http://commerce.senate.gov/hearings/090501Dorgan.pdf> on 19 April 2005.
15. Rich S. FDA Lags on Inspections of Foreign Drug Plants. CongressDaily. 14 December 2004. Accessed at www.govexec.com/dailyfed/1204/121404cdpm1.htm on 20 April 2005.
16. Drug Reimportation Programs Forge Ahead. Employee Benefit News. 1 September 2004. Accessed at www.rxsolutions.com/c/pbi/pbi_view.asp?docid=512 on 19 April 2005.
17. FDA/U.S. Customs Import Blitz Exams Reveal Hundreds of Potentially Dangerous Imported Drug Shipments. U.S. Food and Drug Administration. 29 September 2003. Accessed at www.fda.gov/bbs/topics/NEWS/2003/NEW00948.html on 19 April 2005.

18. Appleby J. Budget Cuts FDA Safety Checks; Calls for Fewer Visits to Inspect Food, Medicine. USA Today. 15 February 2005.
19. Baker C. Would Prescription Drugs Reduce U.S. Drug Spending? Congressional Budget Office. 29 April 2004.
20. The Real Truth About Drug Companies. The Pharmaceutical Research and Manufacturers of America. 2005. Accessed at www.phrma.org/publications/policy/15.09.2004.1078.cfm on 19 April 2005.
21. Tuerck D, Barrett J, Giuffre D, et al. The Impact of Drug Reimportation and Price Controls: The U.S. and Massachusetts. Institute for Policy Innovation. 22 September 2004. Accessed at www.ipi.org on 20 April 2005.



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