

Battles Escalate Over Prescription Drug Imports



Jill Wechsler



Jill Wechsler is *Pharmaceutical Technology's* Washington editor, 7715 Rocton Ave., Chevy Chase, MD 20815, tel. 301.656.4634, jwechsler@advanstar.com.

The campaign to enact import legislation challenges product formulation, industry research and development (R&D), and global drug pricing.

As the political campaign season kicks into high gear, so too is the push to expand access to lower-cost prescription drugs from Canada and elsewhere. Members of Congress are proposing legislation to legalize drug importing and holding hearings on emerging options. States are passing laws and establishing information programs that encourage individuals to obtain drugs from foreign distributors, and local governments are purchasing imports for certain beneficiaries (see Sidebar, "States jump on drug import band wagon"). A federal task force has collected evidence for a report about what policy and legislative actions would be needed for FDA to implement a safe program for importing drugs. The Medicare Modernization Act (MMA), which was approved last December, requires the report by year-end, but political pressures are expected to move the release date up to mid-summer.

Manufacturers strongly oppose import initiatives as a major threat to future drug research and development, acknowledging that higher prices and profits in the United States support the global pharmaceutical research enterprise. Even import advocates privately admit that large-scale purchasing of drugs from other countries is not a real solution to drug access and cost problems in the United States. Ultimately, the expansion of federal government payments for prescription drugs and increased public awareness of international price differentials will significantly change how pharmaceutical manufacturers set global prices and fund the development of new medicines.

Action on Capitol Hill

In recent weeks, leading Senators have rolled out bills designed to legalize drug importing from Canada and other industrial nations. Last year, the House approved legislation sponsored by Representative Gil Gutknecht (R-MN) that permits drug importing from Canada and Europe. Democrats fought to have the measure included in the Medicare bill (MMA), but Republicans managed to replace it with language that permits drug importing, provided that the Department of Health and Human Services (HHS) certifies that such ac-

tivity is safe. To pressure federal officials to address import options seriously, the legislation calls for HHS to conduct a study of what would be required for FDA to establish a safe drug importing system (see Washington Report in *Pharmaceutical Technology's* January issue).

With drug import legislation already approved in the House, the debate on the issue has heated up in the Senate. In April, Senate Finance Committee Chairman Charles Grassley (R-IA) unveiled a bill that enables US residents and distributors to import drugs from Canadian suppliers that are registered with FDA; legal importing would expand to Europe after two years. In addition, the bill includes tax incentives and penalties to encourage drug manufacturers to accept expanded imports: the carrot is an extra 20% R&D tax credit to pharmaceutical companies that agree to supply products to import distributors; the stick is a loss of tax deductions on direct-to-consumer drug advertising for manufacturers that try to limit supplies to known exporters.

Soon after, Senator Byron Dorgan (D-ND) proposed a measure with strong bipartisan support that legalizes drug importing by individuals and commercial entities from Canada and other nations and aims to address safety and regulatory concerns frequently raised by import opponents. The stellar list of cosponsors includes Senator Edward Kennedy (D-MA), former Senate Majority Leader Trent Lott (R-MS), Senate Minority Leader Tom Daschle (D-SD), John McCain (R-AZ), Olympia Snowe (R-ME), and others.

The bill (S. 2328) specifies that foreign imports must be FDA-approved drugs manufactured in plants inspected by the agency. It legalizes personal drug importing from Canada (up to 90-day supplies) immediately and commercial importing by pharmacists and wholesalers registered with FDA within 90 days. Such legal importing would expand in a year to the European Union (as of 1 January 2003), Australia, New Zealand, Japan, and Switzerland. Both Senate bills exempt injectibles, biologics, inhaled therapies, and controlled substances.

The Dorgan bill relies on registered importers to ensure the safety and quality of imported prod-

States jump on drug import band wagon

State governments and public agencies strapped for cash also are seeking ways to reduce spending on pharmaceuticals. As of March 2004, 22 states had filed 47 bills or resolutions containing drug import provisions, according to Frank Palumbo of the University of Maryland's Center on Drugs and Public Policy.

At one end of the spectrum is a Florida bill adopted in June 2003 that aims to thwart illegal imports and an influx of counterfeit products by requiring full pedigrees on imports. The bill also increases authority for officials to crack down on illegal drug distribution. Most state proposals, though, aim to encourage drug importing from

Canada. A West Virginia bill allows the state to explore import options. New Hampshire, North Dakota, and Wisconsin have established Web sites that provide information on "approved" pharmacies and distributors offering access to low-priced drugs from Canada. Minnesota, Illinois, and Maryland are seeking HHS approval of state import plans.

City and local governments have been the most aggressive in implementing import programs. Montgomery, Alabama; Burlington, Vermont; and Springfield, Massachusetts have set up programs to import drugs from Canada for municipal employees and retirees and, so far, FDA has not shut them down.

ucts. Such organizations would have to maintain a full chain-of-custody pedigree on imported products from the point of manufacture through consumer sale. Importers also would have to relabel products in English to comply with FDA requirements and would pay fees up to 1% of import sales to support FDA oversight of import activity. However, this rate would provide only \$10 million to FDA,

based on the current level of \$1 billion of drugs now coming in from Canada—an amount far below what FDA officials consider adequate to police import activity.

Curbs on manufacturing changes

The legislation directly affects drug manufacturing activities through provisions designed to prevent pharmaceutical manufacturers from "gaming" the system by

cutting off supplies to exporters or importers. Recent manufacturer efforts to limit shipments to Canadian exporters have aroused strong criticism from import advocates on Capitol Hill. Under the Dorgan proposal, manufacturers that try to curb imports by raising prices or cutting off supplies to pharmacists, wholesalers, and consumers would violate Federal Trade Commission restraint of trade policies and face treble damage penalties.

In addition, the legislation aims to prevent manufacturers from making postapproval changes in a product's color, dosage form, or place of manufacture that would make the product different from its FDA-approved version and thus illegal to import. To stymie such circumventing tactics, the bill requires manufacturers to apply for FDA approval of drug alterations, including changes in the active ingredient, route of administration, dosage form, strength, formulation, manufacturing establishment, manufacturing process, or "person" that manufactures the drug that would differ from the approved characteristics.

ADVANSTAR
COMMUNICATIONS

For Client Review Only. All Rights Reserved. Advanstar Communications Inc. 2003

Washington Report

Such a policy, however, would undermine FDA efforts to streamline the postapproval manufacturing changes process by flooding the agency with an onslaught of applications for minor drug formulation changes. Making it more difficult for manufacturers to implement manufacturing changes also could compromise the agency's campaign to encourage the adoption of more-advanced systems for producing high quality pharmaceutical products. Such a move to control postapproval manufacturing changes would face immediate legal challenges as a result.

In unveiling the Dorgan bill, Senator Kennedy predicted that the Bush administration and Republicans would offer their own import legislation, which Kennedy said would be watered down and fall far short of what was needed to do the job. Senator Judd Gregg (R-NH), chairman of the Senate Health, Education, Labor, and Pensions (HELP) Committee, has developed a bill that gives FDA more control over drug imports (that were initially limited to Canada) and is holding hearings on the various proposals.

Gathering evidence

FDA and HHS officials as well as manufacturers prefer that Congress delay legislative action until the HHS drug import task force completes its report. The panel, as required by the MMA, has held a series of "listening sessions" to gather testimony from consumer advocates, healthcare purchasers, manufacturers, distributors, international stakeholders, and others. The aim is to obtain information about what legal and regulatory policies are needed for FDA to ensure the safety and quality of imported or reimported drugs. To this end, the panel, which is chaired by United States Surgeon General Richard Carmona, is examining

- changes in the drug distribution chain that could ensure safe imports
- the ability of anticounterfeiting technologies to guarantee import safety
- the scope of unapproved drugs entering the United States by mail
- whether foreign health agencies can ensure the safety of drug exports
- the cost for federal agencies to inspect imports and ensure their safety

- the potential impact of increased importing on United States drug prices, patents, and R&D.

At the first session, consumer representatives maintained that the United States could establish a safe importation system. Next, pharmaceutical manufacturers offered evidence regarding how legalizing imports would allow more counterfeit products into the country and reduce R&D incentives. The governor of Wisconsin appeared at the third session to explain his state's efforts to allow individuals to obtain drugs from Canada through an Internet information service. At the next session, pharmacists from Canada provided evidence on how drug importation will harm the Canadian healthcare system. At the task force hearing on 5 May, CVS Chairman Thomas Ryan made the surprise announcement that he now supports legalized drug importing as a temporary way to gain relief from high US drug prices. Ryan's comments reflect the growth in drug importing by individuals using Web sites that

ADVANSTAR
COMMUNICATIONS

For Client Review Only. All Rights Reserved. Advanstar Communications Inc. 2003

Washington Report

shut out retail pharmacists. His long-term solution lies in adopting a global pricing model that is more fair for US consumers.

FDA officials continue to cite concerns about the safety and unknown quality of drugs obtained from foreign sources. At a Senate Finance Committee hearing in April, FDA Associate Commissioner William Hubbard reiterated FDA data about the large volume of illegal, unapproved drugs already entering the United States through the mail. He said that legalizing imports would only spur more drug counterfeiting and do little to make drugs more affordable for patients.

Instead of legalizing imports, US trade officials called for efforts to convince other nations to remove price controls on drugs. Such actions would spur innovation in Europe as well as enhance worldwide competition in the pharmaceutical industry.

Separately, FDA has been intensifying its campaign against pharmacy Web sites that engage in illegal marketing activities, including the sale of controlled substances, counterfeits, imports, and other unap-

proved products. An FDA "sting" operation in January led to charges against importers in Texas. In February, FDA took action against three foreign Web sites associated with the sale of counterfeit contraceptive patches that had no active ingredient. FDA acknowledges that individuals who go to Canada and purchase drugs directly from a pharmacy probably obtain safe and effective products. However, Internet and mail-order purchases open the door to counterfeits and products from unknown sources and countries.

In this area, members of Congress are backing FDA's crackdown on illegal Web sites that promote access to unsafe pharmaceuticals. Representatives Henry Waxman (D-CA) and Tom Davis (R-VA) are sponsoring a bill that establishes a certification process for Internet pharmacies. Another House bill aims to halt illegal drug use by requiring manufacturers of controlled substances and highly abused drugs to insert electronic identifier technology in these products by 2006; all drugs would have such tracking devices by 2008.

Push for lower prices

Because large-scale drug importing will be cumbersome and costly to oversee, and individuals will not realize huge savings from a more-regulated import system, the larger aim of import advocates is to pressure drug manufacturers to lower their prices in the United States. The real issue is "access and affordability of prescription drugs," commented Robert Freeman, executive director of public policy at Astra Zeneca, during the conference, "Innovation and Drug Reimportation," in Washington, DC (19-20 April 2004). Drug reimportation is a political response to the need for certain individuals—the uninsured, underinsured, and retirees that pay cash for drugs—to gain access to affordable medicines, Freeman explained. With international drug prices now more transparent because of the Internet and global economy, Freeman expressed skepticism that pharmaceutical manufacturers will be able to sustain a system that sets widely different prices for different markets.

Expanded drug importing is not the answer, Freeman maintained, noting that

ADVANTAR
COMMUNICATIONS

For Client Review Only. All Rights Reserved. Advanstar Communications Inc. 2003

Washington Report

under such a system, wholesalers and retailers will profit, and consumers will not gain meaningful savings. Commercial importing would merely redistribute profits from pharmaceutical manufacturers to distributors, as seen in the European Union's experience with parallel trade.

While industry critics scoff at manufacturer claims that importing will dry up funds to support R&D, Freeman explained how such policies would lead to a "higher degree of risk aversion." Instead of expanding internal research programs, pharmaceutical companies would be more likely to partner with small biotechnology firms and niche companies to explore new treatment areas. Large manufacturers would focus more on developing new indications for existing therapies, and new R&D projects would have to meet higher sales thresholds for management to justify the investment.

Robert Helms of the American Enterprise Institute (Washington, DC), explained that manufacturers respond to price controls by

- reducing total R&D investment

- concentrating on drugs that treat large patient populations and dropping small market projects such as vaccines
- increasing short-run projects versus long-term projects
- dropping investment in higher-risk projects.

In addition, analysts note that such trends may shape pharmaceutical R&D in ways that patients may not like such as increasing investment in nonreimbursable erectile dysfunction and cosmetic treatments.

Time for action?

Freeman predicted that Congress will enact legislation this year that legalized drug importation to some degree. A few weeks later, HHS Secretary Tommy Thompson echoed this expectation. Senate Majority Leader Bill Frist (R-TN) promised Dorgan and other import advocates in March that he would schedule full Senate consideration of drug import legislation as part of an agreement to gain Senate confirmation of Mark McClellan as administrator of the Centers for Medicaid and Medicare Ser-

vices. And with the presidential elections looming in November, President Bush does not want to be painted by Democrats as blocking poor Americans from perfectly good low-cost drugs in Canada. At a minimum, import advocates will try to add drug import provisions to FDA's 2005 budget appropriations legislation now moving through Congress.

With Medicare poised to become a major purchaser of drugs in less than two years, McClellan recently has been talking about the need to access affordable medicines. During the confirmation process, he acknowledged to Senators that it might be possible to support a drug import program that was limited in scope and in type of drugs. FDA would have to receive more money, more personnel, and more enforcement authority to effectively monitor drug imports and detect counterfeit or unapproved products.

At the same time, Congress may not have time this year to agree on a measure addressing this controversial issue. Craig Fuller, president of the National Association of Chain Drug Stores (Alexandria, VA), recently raised this logistical issue, noting that the emergence of competing proposals in the Senate and continued opposition from Republican leaders, may delay deliberations until after the fall elections.

Although most observers do not believe that a commercial import system as outlined in the Dorgan bill could ever be implemented without enormous expense, it sets a marker for a more flexible approach toward legal importing by individuals for personal use and a more regulated system for wholesalers and pharmacists to bring in certain prescription drug products. Even if Congress does not act this year, the escalating debate over drug pricing heralds significant change in the political environment related to pharmaceutical marketing. Legislative proposals raise the possibility of changes in tax policy and increased liability exposure for manufacturers.

At the drug import conference, Economist John Graham from Canada described drug import legislation as "a stepping stone" towards US price controls. Freeman agreed that restructuring pharmaceutical price mechanisms worldwide would reduce current international price disparities. But he also wondered if US policymakers really want a system in which poor nations pay the same price for medicines as do rich ones. **PT**



For Client Review Only. All Rights Reserved. Advanstar Communications, Inc.