Critics, Supporters Argue Importation Before HHS Task Force

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BETHERSDA, MD, 24 May 2004 — Americans could be exposed to unregulated medications, drug makers would reduce research and development because of profit cuts, and Canadians could face increased prices and product shortages if importation of prescription drugs from Canada is legalized, opponents asserted before a panel of federal officials at a series of invitation-only meetings.

Supporters of importation warned that many people are going without needed medications because of unaffordable prices in the U.S. market and accused pharmaceutical companies of waging an expensive, highly coordinated scare campaign to convince Americans that buying drugs from Canada is unsafe.

A 13-member task force, led by Surgeon General Richard H. Carmona, met with various stakeholders over the past several weeks to gather and discuss information about importation as part of a Department of Health and Human Services (HHS) comprehensive study mandated by Congress under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

The panel also heard from the public at an open hearing on April 14, during which Gary Stein, director of federal regulatory affairs for the American Society of Health-System Pharmacists (ASHP), warned that the debate about whether to allow Americans to buy prescription drugs at lower prices outside the country has obscured the issue of protecting the nation's drug supply.

"A growing illegal drug trade, including counterfeit medications, rogue internet sites, and efforts to open U.S. markets to drugs imported from abroad, have all raised questions regarding the FDA's ability to respond" to the challenges of securing the pharmaceutical supply chain, he said.

FDA's regulatory system is the world's "gold standard" of drug approval, Stein declared.

"To assure the safety of imported products, the FDA will need significantly more resources to examine those products for quality, purity, safety, and effectiveness," he affirmed.

Stein also warned that terrorists could use "lenient" importation rules to introduce harmful agents into the U.S. drug supply chain.

"Is this issue not being considered a priority because it hasn't happened yet? Do we have to wait?" he asked.

Stein told the task force that ASHP's House of Delegates will vote in June to reaffirm the Society's policy to oppose importation of pharmaceuticals except in cases in which the Food and Drug Administration determines it would be necessary for the health and welfare of United States citizens.

ASHP was also invited by the task force to present information at a May "listening session."
Counterfeit experience. San Francisco resident Rick Roberts, testifying at the public hearing, told the task force that when Americans go outside of FDA's jurisdiction and the U.S. drug supply chain "we create opportunities for counterfeiters.

Roberts was exposed to counterfeit somatropin in 2000. He said that, even though Serono Inc., which markets the product under the name Serostim, had announced a recall, Roberts's pharmacy failed to inform him that he had received fake drugs.

Roberts's physician was also unaware of the recall.

After Roberts discovered information about the recall on the Internet, he contacted FDA.

But FDA officials did not respond to Roberts until after articles about his experience appeared in several news publications.

State and federal investigators, he said, are still tracing the source of the phony somatropin, adding that the product he received had changed hands among at least three licensed secondary wholesalers in New York, Nevada, and Florida.

The name of the Florida wholesaler, Roberts noted, was Rkcus—which spelled backwards is "suckers."

Roberts admitted in an interview that he was "invited" to attend the public hearing by the trade group Pharmaceutical Research and Manufacturers of America (PhRMA), which paid for his travel expenses.

Representatives from drug companies, including Eli Lilly and Company and Pfizer Inc., and distributors also warned the task force at an April 5 listening session about concerns that importation would make the American drug supply vulnerable to counterfeiters.

Wholesalers' concerns. Kurt J. Hilzinger, president and chief operating officer of AmerisourceBergen Corp. and a member of the board and executive committee for the Healthcare Distribution Management Association, testified at the April 14 hearing that, if importation is legalized, FDA should hold foreign manufacturers to the same standards as U.S. drug makers for evaluating when products are recalled.

"Who will have responsibility for initiating, regulating, and monitoring international recalls?" he asked, and further questioned if FDA would have jurisdiction and oversee over a foreign firm's recall plan.

"What will happen if foreign-originated product is recalled but its domestic counterpart is not—will this require wholesalers and pharmacies to maintain separate inventories? If so, this implies a whole new set of procedures and costs that should be factored into your study."

Wholesalers are "best positioned" to help maintain the safety and security of the nation's drug supply, Hilzinger declared.

But, he added, "importing product from foreign sources introduces significant challenges that must be addressed to ensure the broad safety of imported products while maintaining the desired cost benefits for consumers."

NYC investigation. Bernard Kerik, a former New York City police commissioner, told the task force at the public hearing that he has partnered with the city's former mayor, Rudolf Giuliani, to "conduct an independent review of the safety issues related to the wholesale importation of medicines from outside the U.S."

"We are making every effort to speak to people and groups on both sides of the issue, including those who support it as well as those who oppose the importation," he said.

As part of their research, Kerik said, he and Giuliani, accompanied by Senator Norm
Coleman (R-Minnesota), visited a mail facility in Queens, New York, at which they observed "thousands and thousands of parcels containing prescriptions, including controlled substances, being shipped through the U.S. mail service."

"Many of the packages were from such countries as India, Pakistan, Brazil, and the Netherlands," he claimed. "Many of the drugs were not FDA-approved, some expired, others did not have any dosage information or were improperly packaged, some that required refrigeration were clearly not refrigerated, and some were injectable."

Investigators at the Queens mail facility, Kerik said, uncovered "one highly sensitive cancer drug that requires very close doctors' supervision" that had been shipped through the mail directly to a patient.

"It was obvious that, contrary to popular opinion, medicines being purchased over the Internet are not just coming from Canada and, based on visual inspection, are not FDA-approved," he said.

Kerik admitted in an interview that he and Giuliani had been retained by PhRMA to conduct the study—a fact he failed to mention during his public testimony at the April 14 hearing.

Midwest arguments. Wisconsin Governor Jim Doyle reminded the task force that HHS was given the authority under the Medicare reform act, signed into law last December, to allow "safe" importation from Canada of drugs made by FDA-approved manufacturers.

"I hope that this task force will recommend that the administration use its authority to do just that," he said.

Doyle said he is "disappointed that the federal government has not done more to address this dramatic inflation in prices or to provide meaningful prescription drug coverage to those who need it most."

Many Wisconsin residents, he said, struggle with the high cost of prescription drugs and are often "forced to make the inhumane and unbearable choices between food and medicine, or skipping a dose here or there."

But across the border, he contended, Canadians can buy the same medications available in the United States for "a fraction of what we pay."

Because the federal government has failed to take action about the high costs of prescription drugs, Doyle asserted, states, like Wisconsin, have been "forced to take the lead."

In response to "overwhelming demand" from residents, he said, Wisconsin launched a Web site in February that lists Canadian pharmacies that "our state has visited and found to be safe, reputable, and reliable."

"Over the last six weeks, we have had 87,000 visitors to the Web site—an average of 2,000 visitors a day trying to find help with affordable drugs," Doyle said.

But in March, William K. Hubbard, FDA's associate commissioner for policy and planning, warned Doyle in a three-page letter that the Web site was encouraging Wisconsin residents to "purchase unapproved, illegal drugs from foreign pharmacies."

"We strongly believe that the endorsement of the practice by a public official such as yourself undermines one of our nation's key consumer protection statutes and places your constituents at unnecessary risk of harm from unregulated pharmaceuticals," Hubbard admonished.

Doyle fired back at the April hearing saying he found it "amazing" that "FDA has time to send out press releases attacking our Web site. It has had time to send staff to Wisconsin
to hold press conferences criticizing our efforts, but not to actually work with us to put [importation] into place. It is a story of missed opportunities and misplaced priorities, and it is a disservice to the people of this country."

The Wisconsin governor accused federal officials of "doing the bidding of the drug lobby."

"Someone has to stand up to deal with the incredible soaring prices of pharmaceutical drugs, and somebody in this task force is in the position to do it, to say that we are going to look out for the people of the United States, the people of the state of Wisconsin," he pleaded.

Pharmacist Ram Kamath, special advocate for prescription drugs for the Illinois Department of Public Aid, said his state has designed an importation plan for state employees, not yet implemented, that would include pharmacist-provided medication counseling and monitoring.

The state has sought a waiver from HHS to implement a pilot program but has not received an answer.

Northern exposure. Barbara A. Wells, executive director of Canada's National Association of Pharmacy Regulatory Authorities, told the task force at the April 27 invitation-only listening session that cross-border trade of drugs could negatively affect Canadians' pharmaceutical supply and prices.

She also contended that it could harm her country's supply of pharmacists.

Wells asserted that increased pressure to fill U.S. prescriptions could result in Canadian pharmacies seeking alternate suppliers that could potentially introduce unapproved or counterfeit drugs into Canada's supply chain.

However, she acknowledged in an e-mail response to questions, she does "not have any evidence that this has happened."

Economic effects. Iain M. Cockburn, professor of finance and economics in the School of Management at Boston University in Massachusetts and a research associate of the National Bureau of Economic Research, argued at the April 27 meeting that large-scale importation of drug products into the United States would limit the ability of drug companies to maximize revenues from global sales of their products.

"Access to drugs at the lower prices charged in some countries may give an immediate economic benefit to some U.S. purchasers in the short run," he said. But importation would "seriously damage" consumers in the long run by weakening incentives for pharmaceutical companies worldwide to invest in research and development, he maintained.

Indeed, the entire five-member panel of economists who attended the April 27 invitation-only meeting—all opponents of importation—agreed with Cockburn's argument.

Craig Stevens, public affairs officer in the Surgeon General's Office, said that the task force had invited three other experts in pharmaceutical economics who had "written in favor of importation." But because of scheduling conflicts, they were unable to attend, he said.

"We are actively seeking a series of diverse opinions, and we're trying to get the best information available to see if and how it's possible to import drugs safely and effectively," Stevens said.

But Cockburn's Boston University colleague, Alan Sager, professor of health services and director of the university's Health Reform Program, said that he was not invited to the April 27 listening session until one day before the meeting when he received a phone call from an FDA official.
"This short notice does not seem to constitute an invitation," he stated in an e-mail response to questions, adding that the FDA official "politely" said that the task force "did not expect I would be able to attend on such short notice."

Sager and a colleague released a report on April 15 showing that importation of drugs from Canada may not pose the presumed financial threat to pharmaceutical companies that manufacturers and others have contended.

"Indeed, drug makers could even benefit," the report stated.

"We have calculated that if 44.53 percent or more of the money spent for prescriptions bought by Americans in Canada is for new prescriptions, those not formerly purchased in the United States, the drug makers actually make more money when importation is allowed," the researchers reported.

The 44.53% new prescription share is the point at which the added profits from selling more drugs from Canada, even at discounted Canadian prices, offsets the loss in revenue on forgone sales of high-priced U.S. drugs, the report stated.

The two other experts in pharmaceutical economics invited to, but unable to attend, the April 27 meeting—Stephen W. Schondelmeyer, professor and head of the Department of Pharmaceutical Care and Health Systems and director of the PRIME Institute at the University of Minnesota, and David Dranove, professor at Northwestern University's Kellogg School of Management in Evanston, Illinois—said that they were invited less than one week before the meeting.

—Donna Young