Importation Reports Spur More Debate About Drug Prices

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BETHESDA, MD, 19 January 2005 — Bush administration officials in two December 2004 reports suggested that American consumers faced with paying high prices for prescription drugs should rely more on generic medications and prescription drug discount cards rather than risk their health by seeking lower-priced products outside the United States.

Officials advised uninsured consumers and seniors paying for expensive products unavailable in generic equivalents to shop around and compare prices at pharmacies in their local communities.

But Alan Sager, director of the Health Reform Program at Boston University School of Public Health in Massachusetts, contended that, while there are safety concerns involved in importing medications, the Bush administration's recommendation to price shop and "buy this pill here and that pill there" disrupts the patient–pharmacist relationship—also putting patients at risk.

Consumers, he argued, should be able to buy affordable medications at their neighborhood pharmacy where "one expert would know what each patient is taking and could coordinate [their medications] and watch for interactions."

Sager charged that the Bush administration's reports are "unhelpful" in solving the crisis faced by many Americans who are unable to afford the vital medicines prescribed by their physicians.

Consumers are taking the risk of importing drugs from Canada and other foreign countries, he maintained, because they believe that "getting the pills is better than not getting the pills."

Several legislators—Republicans and Democrats—criticized the Bush administration for failing to consider all sides of the importation debate in its reports to Congress.

But, Sager said, lawmakers have also failed U.S. consumers by being "stuck" on the argument of whether drugs should be imported rather than finding solutions to lowering drug prices.

The government reports, which were delivered two weeks late to Congress, were mandated as part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

The Secretary of the Department of Health and Human Services (HHS) was charged with analyzing the potential impact of importation on the well-being of Americans, health care spending, and the research and development of new drugs.

Secretary Tommy G. Thompson assigned the task of developing the HHS report (PDF) to a 13-member panel of government officials headed by Surgeon General Richard H. Carmona.

The Secretary of the Department of Commerce (PDF) was tasked with examining the effect that medication-price controls in foreign countries have on intellectual property laws, innovation, generic drug competition, and research and development.

In a December 21 joint letter (PDF) to congressional leaders, Thompson and Commerce Secretary Donald L. Evans threatened that if Congress passed importation legislation that failed to address the safety concerns outlined by the Bush administration or attempted to legislate price controls, the president's senior advisers would "recommend a veto."

Can importation be made safe? Agreeing with many opponents of prescription drug importation, Bush administration officials concluded that making importation safe for consumers would tax the government's resources and ultimately provide little savings for consumers.

Importation increases the opportunities for counterfeit and other substandard drugs to enter and be dispersed into the U.S. drug distribution system, officials warned.

The only scheme that would be feasible, the HHS task force maintained, is commercial importation in which drugs are purchased from Canada by pharmacies and wholesalers for resale to consumers.

The panel of government officials frowned on legalizing "personal importation" in which consumers could individually import drugs.
Making personal imports of medications lawful, officials cautioned, could create numerous vulnerabilities in the drug distribution system, "making it extraordinarily difficult to ensure that imported drugs are safe and effective."

Using data from IMS Health, the HHS panel estimated that it would cost the government $3 billion to regulate a personal importation program.

If personal importation is legalized, the HHS report authors added, government inspectors would have difficulties distinguishing packages of drugs shipped by regulated Internet pharmacies from those coming from rogue online pharmacies, thereby increasing the safety risks for consumers.

Recalls of products also pose another safety hurdle for regulators and manufacturers if importation is authorized, the HHS report noted.

Thomas J. McGinnis, FDA's director of pharmacy affairs, said that recalls are "fairly easy with the domestic supply system."

But, he said, "with the international supply system, it will be a little bit more tricky."

Legislators, McGinnis said, would need to mandate that manufacturers notify FDA when a product is recalled in a foreign country.

Consumers who illegally import prescription drugs, he warned, risk not knowing when a manufacturer or health agency has issued a recall notice about a product in a foreign country.

Douglas J. Schneckholf, director of pharmacy practice managers at the American Society of Health-System Pharmacists (ASHP), said that overall, the HHS report is consistent with ASHP's position that "drug importation that does not meet FDA-approval standards would bring a great deal of risk to patients."

"We were glad to see the recommendations of the task force concurred with our position," he said, adding that the report notes the essential role that pharmacists can play in helping consumers find affordable medications and prescription drug assistance programs.

Schneckholf testified on May 14, 2004, at one of five HHS importation task force listening sessions. The HHS panel held the invitation-only sessions over several weeks last spring to gather information about importation from consumer-advocacy groups, health care purchasers, professional health care provider organizations, industry and distribution representatives, and international stakeholders.

The panel also heard from the public at an open hearing on April 14, 2004, during which Gary Stein, ASHP's director of federal regulatory affairs, testified.

ASHP's House of Delegates in June 2004 affirmed that the Society should advocate for the continuation and application of laws and regulations enforced by FDA and state boards of pharmacy that (1) maintain the integrity of the pharmaceutical supply chain and avoid the introduction of counterfeit products into the United States, (2) provide for continued patient access to pharmacist review of all medications and preserve the patient–pharmacist–prescriber relationship, and (3) provide adequate patient counseling and education, particularly to patients taking multiple high-risk medications.

**Impact of technology.** Although the HHS report noted that FDA in its February 2004 counterfeit drugs report urged widespread adoption by the drug industry of track-and-trace and authentication technologies by 2007 to protect the U.S. drug supply, the importation task force asserted that use of the technologies "may increase the costs of drugs, whether domestic or imported."

However, the panel admitted that it did not know the "extent" of any potential increased costs associated with implementing anticontrolling technologies.

Further, the importation task force said it had "received inadequate information to assess the potential costs borne" by the drug industry for adopting the technologies.

However, at a November 15, 2004, press conference during which FDA officials announced new compliance policy guidelines for companies testing the use of radio frequency identification (RFID), one official contended that as more companies adopt and use RFID, costs of the technology would "dramatically" drop.

The importation task force surmised that even with anticontrolling technologies implemented on imported products, "it is possible that consumers will still be exposed to counterfeit, adulterated, or otherwise substandard drug products that are shipped into the U.S."

**Do lower prices reduce research spending?** Both government reports warned that importation could lead to reduced research and development by drug makers because of
lower profits.

But, Boston University's Sager argued, the Bush administration in both reports, which he described as "darkly pessimistic," has assumed without factual evidence that by making lower-priced drugs available to consumers, whether through importation, negotiations, or price controls, drug companies would have a reduction in profits.

"That's an empirical question that hasn't been answered," he said.

"When prices fall, many more people can afford to fill many more prescriptions," Sager proclaimed. Drug companies, he maintained, could recoup lost revenue from price cuts through higher volumes of products sold.

"It's like driving a stick-shift car," Sager explained. "If you don't work the accelerator and clutch together you either spin your wheels or stop. So volume is the gas, the clutch is the price. You ease up on price, you step on the gas, and speed forward. We could then afford to fill all prescriptions for all Americans, and the only increase in spending would be that necessary to cover the actual cost of manufacturing, which is tiny."

A free market? The Bush administration's argument that negotiating or setting price controls for drugs would infringe on a free-market system, he asserted, is weak.

Between patents owned by the drug companies and the degree of economic concentration in the pharmaceutical industry, Sager charged, "only the most naive student in Economics 100 could imagine that that kind of market dominance, or oligopoly, is even a distant cousin of a free market."

As for the government's warnings about reduced spending on research, Sager said, most drug companies, which he claimed have artificially bolstered their profits by relying on the development of "me-too" drugs—medications that are similar to other products already on the market that treat the same disease—have in recent years invested very little in breakthrough research.

He called on the government to provide performance-based incentives for drug companies to invest in breakthrough research.

But, he asked, "What good are tomorrow's medications, let alone today's, if 70 million Americans have no insurance for prescription drugs? What good are the meds if we can't afford to buy them?"

—Donna Young