Task Force Raises Safety, Cost Concerns on Drug Importation

BY MARY ELLEN SCHNEIDER
Senior Writer

A limited commercial program that would import drugs from Canada is feasible but would result in limited savings for consumers, members of a government task force on drug importation said at a press briefing sponsored by the Health and Human Services Department.

The HHS-convened task force dismissed the idea of personal importation of drugs from other countries as being extraordinarily difficult and costly to implement safely. It could cost as much as $3 billion a year to regulate personal importation, according to a letter sent to congressional leaders from the secretaries of HHS and the Commerce Department.

"Any plan to permit importation must be limited to commercial importation of a discrete number of high-volume, high-cost prescription drugs from a country with equivalent drug safety protections," according to the secretaries. "These drugs must have the same level of safety and effectiveness as FDA-approved products."

In the letter, Bush administration officials outlined the requirements of such a system. For example, it should require drug pedigrees, limit ports of entry and distribution channels, and allow commercial importation only from licensed foreign wholesalers to authorized sellers in the United States.

A commercial program would have to be limited to those prescription drugs that are mostly likely to yield savings, such as a high-volume drug without a U.S.-approved generic. The administration is also asking Congress to exclude drugs or classes of drugs that could pose increased safety risks in an importation program, such as controlled substances or drugs that require refrigeration during shipping. And the program must avoid "anticompetitive provisions" including "forced sale" clauses and other types of price controls.

The letter also warns Congress that if its members pass legislation that stifles competition or fails to address safety concerns, the president's senior advisors will recommend a veto.

None of the legislation previously introduced in Congress would meet this criteria since most of it deals with personal importation of drugs, a senior administration official said in a teleconference announcing the release of the report.

The American Medical Association recently took a similar position. The group said that it supports importation of prescription drugs by wholesalers and pharmacies, provided that the drugs have been FDA approved and are part of a closed distribution chain. AMA does not support personal importation via the Internet until patient safety can be assured.

"Patient safety must remain the overriding concern as we work to make prescription drugs more available and affordable for patients. Patients must be protected from unapproved drugs that could be unsafe, expired, counterfeit, adulterated, misbranded, or inappropriately labeled," AMA Trustee Edward L. Langston, M.D., said in a statement.

But Sen. Byron Dorgan (D-N.D.), a leading proponent of the importation of drugs from other countries, said he never had much confidence that the HHS study would be objective and plans to introduce reimportation legislation.

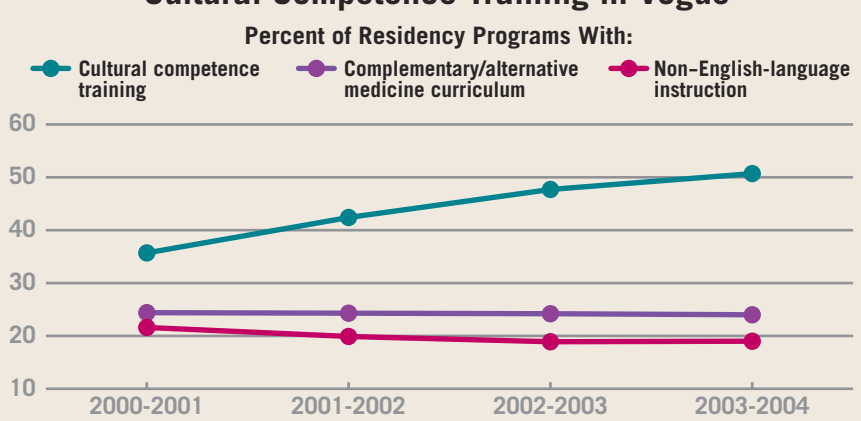
"Millions of American obtain prescription medicines from Canada and other countries every year and do so safely," Sen. Dorgan said in a statement. "The federal government itself is buying flu vaccine from abroad right now. The only thing endangered by allowing Americans access to lower priced FDA-approved medicines from abroad is the incredibly large profits of the drug companies who overprice their medicines in our market, just because they can."

The HHS task force was formed early in 2004 to address questions posed by Congress in the Medicare Modernization Act. The law includes a provision to allow the importation of prescription drugs from Canada if the HHS secretary certifies that the drugs pose no additional risk to public health and safety and would offer significant savings to U.S. consumers. ■

The HHS Task Force report on prescription drug importation is available online at www.hhs.gov/importtaskforce.

DATA WATCH

Cultural Competence Training in Vogue



Note: Based on surveys of about 8,000-9,000 residency directors per academic year.
Source: JAMA 2004;292:1032-7

KEVIN FOLEY, RESEARCH

POLICY & PRACTICE

Improper Payments Increase

Medicare made approximately $20 billion in improper payments in fiscal year 2004, a report from the Centers for Medicare and Medicaid Services has found. The sum included $900 million in underpayments to providers due to errors made by insurers and $20.8 billion in overpayments made to providers. Medicare hopes to cut the rate of erroneous payments by more than half, to 4%, in 2008 by conducting more extensive payment reviews and by implementing other quality control measures. "We have made significant strides in how we measure the error rate in Medicare payments, and that will enable us to do even more to bring it down," commented Mark McClellan, M.D., CMS administrator. "We have much better data that will help us pinpoint problems and allow us to work with the Medicare contractors and providers to make sure claims are submitted and paid properly."

Patients Turn to CAM

Discouraged by the high cost of conventional treatments, 6 million Americans turned to alternative medicines in the past year to treat conditions such as depression and chronic pain, the Center for Studying Health System Change reported. People using these approaches to save money are often uninsured and usually lack a medical home. Although the price is right, these alternative treatments "may be of questionable value," said HSC President Paul Ginsburg, Ph.D. About 63% of the respondents said they used herbal remedies, yet two of the most popular remedies—St. John's wort and kava—have been known to cause serious side effects. In more than half these cases, a conventional medical professional was unaware of a patient using an alternative treatment. The study was based on the 2002 National Health Interview Survey, a government survey that includes information on 31,000 adults.

Treating Men's Depression

Improving primary care treatment for depression might help narrow the "gender gap" that leaves a greater proportion of depressed men untreated, according to a study from the Rand Corp. For their study, researchers assigned 46 primary care practices nationwide to provide either usual care for depression or to provide an improved treatment regimen that educated providers and patients about available depression treatment. Among practices that used an improvement program, rates of depression treatment increased for both sexes, but some treatment approaches increased care for men more than for women. "The findings suggest that quality improvement programs may help reduce the treatment disparity seen among the estimated 6 million depressed men in the United States," the researchers said.

Bioterrorism Preparedness Update

States have made progress in protecting Americans from a bioterrorist attack, but they still have a long way to go, a report from Trust for America's Health (TFAH) concluded. Nearly 60% of states do not have adequate numbers of laboratory scientists to test for anthrax or the plague in the event of a suspected outbreak, and two-thirds do not electronically track disease outbreak information by national standards, making early warning of disease threats difficult. In addition, only six states are adequately prepared to distribute vaccines and antidotes in an emergency. Although planning for a flu pandemic has improved, 20 states still do not have publicly available response plans in place. To improve bioterrorism and public health preparedness, TFAH, a nonprofit, nonpartisan organization that focuses on disease prevention, recommended a systematic review of preparedness gaps, conducting practice drills to assess capabilities and vulnerabilities, and limiting liability to encourage vaccine development and protect health care workers.

Concern About Iodide Stockpile

The Department of Health and Human Services needs to do more to ensure an adequate stockpile of potassium iodide (KI) in case of an accident or attack involving a nuclear power plant, Rep. Edward J. Markey (D-Mass.) said in a letter to HHS. Rep. Markey sponsored an amendment to the Bioterrorism Act directing HHS to make KI available to state and local governments for distribution to anyone living within 20 miles of a nuclear power plant. "I am deeply disappointed by the continued delays in implementing this program," Rep. Markey wrote. He noted that after the Chernobyl nuclear accident, numerous thyroid cancers occurred in Belarusian children, but none occurred in Polish children, because Poland quickly administered KI. The American Thyroid Association also criticized HHS, charging that the draft guidelines HHS issued to deal with the problem "interfere with, rather than assist and encourage, states and localities in obtaining KI as a preparedness measure."

No Global Cloning Ban

The United Nations could not come to a consensus to approve a global ban on all forms of human cloning. The United States and Costa Rica had led an effort to ban all cloning, including so-called therapeutic cloning, but the treaty did not draw enough support. But groups such as the Coalition for the Advancement of Medical Research have urged the United Nations to reject a wide-ranging ban that would apply to cloning that could aid in medical research and the development of therapies. "We're very gratified that the U.N. has backed away from an overreaching treaty that could harm medical research and hinder possible cures for millions throughout the world," Daniel Perry, president of the coalition, said in a statement.

—Jennifer Silverman