HHS Raises Concerns About Drug Importation

BY MARY ELLEN SCHNEIDER
Senior Writer

A limited commercial program to 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. 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.

If Congress passes legislation that stifles competition or fails to address safety concerns, the letter warns that 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 on drug importation. The AMA supports importation of prescription drugs by wholesalers and pharmacies, provided the drugs have been FDA approved and are part of a closed distribution chain. The 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 Americans obtain prescription medicines from Canada and other countries every year and do so safety," 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."

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 that would 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 is available online at www.hhs.gov/importtaskforce.

INDEX OF ADVERTISERS

CLASSIFIEDS

Also Available at www.eskinandallergynews.com

PROFESSIONAL OPPORTUNITIES

Disclaimer

SKIN & ALLERGY NEWS assumes the statements made in classified advertisements are accurate, but cannot investigate the statements and assumes no responsibility or liability concerning their content. The Publisher reserves the right to decline, withdraw, or edit advertisements. Every effort will be made to avoid mistakes, but responsibility cannot be accepted for clerical or printer errors.

LABORATORIES