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HHS NAMES MEMBERS TO TASK FORCE ON DRUG IMPORTATION

HHS Secretary Tommy G. Thompson today named 13 people to serve on the new Task Force on Drug Importation that is exploring how drug importation might be conducted safely and its potential impact on the health of American patients, medical costs and the development of new medicines.

Surgeon General Richard H. Carmona will serve as the task force's chairman. The panel includes representatives from across HHS, as well as from other parts of the federal government with knowledge or involvement in drug importation issues. The task force may consult other federal officials as well.

"Under Dr. Carmona's leadership, this task force will fully examine the issues surrounding drug importation to determine how to assure consumers that such imported drugs are safe and effective," Secretary Thompson said. "We haven't been able to provide those safety assurances as required by law and with available resources. The task force will study if drugs can be imported safely and, if so, what resources would be needed to ensure safety."

Secretary Thompson also announced the dates for the task force's five listening sessions with groups and individuals who would be affected by drug importation. The first meeting will take place Friday, March 19, and will feature speakers from at least a dozen invited consumer groups.

The dates of the other listening sessions are: April 2 with health care purchasers; April 28 with professional health care providers; May 6 with industry representatives; and May 14 with international stakeholders.

In addition, the task force will hold a public hearing on April 14 to allow members of the general public to present their views on the issue. The hearing will take place in the Natcher Auditorium at HHS' National Institutes of Health in Bethesda, Md. Information about participating in the public hearing is available at <http://www.fda.gov/OHRMS/DOCKETS/98fr/04n-0115-nm00001.pdf>.

"Secretary Thompson asked the task force to assess the issue of drug importation safety and the associated public health issues," Dr. Carmona said. "I am looking forward to working with task force members as we conduct a fair and objective evaluation based on the best science and information available."

In addition to Dr. Carmona, the task force members are:

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- Jayson P. Ahern, assistant commissioner in the Office of Field Operations, U.S. Customs and Border Protection, Department of Homeland Security.
- Alex M. Azar II, HHS general counsel;
- Josefina Carbonell, HHS assistant secretary for aging;
- Lester M. Crawford, DVM, Ph.D., FDA deputy commissioner;
- Betty James Duke, administrator for HHS' Health Resources and Services Administration;
- Mark B. McClellan, M.D., Ph.D., incoming administrator for HHS' Centers for Medicare & Medicaid Services;
- Mike O'Grady, HHS' assistant secretary for planning and evaluation;
- William Raub, HHS' deputy assistant secretary for public health emergency preparedness;
- Tom Riley, public health branch chief at the White House Office of Management and Budget;
- Amit K. Sachdev; acting FDA deputy commissioner for policy;
- Elizabeth A. Willis, chief of the Drug Operations Section, Office of Diversion Control, U.S. Drug Enforcement Administration; and
- Colette Winston, a trial attorney at the Department of Justice.

The task force's members ultimately will offer recommendations to Secretary Thompson on how best to address the key questions posed by Congress as part of the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The legislation directed HHS to complete a study by December 2004 to address the following issues related to drug importation:

- Identify the limitations, including limitations in resources and in current legal authorities, that may inhibit the Secretary's ability to certify the safety of imported drugs.
- Assess the pharmaceutical distribution chain and the need for, and feasibility of, modifications in order to assure the safety of imported products.
- Analyze whether anti-counterfeiting technologies could improve the safety of products in the domestic market as well as those products that may be imported.
- Estimate the costs borne by entities within the distribution chain to utilize such anti-counterfeiting technologies.
- Assess the scope, volume and safety of unapproved drugs, including controlled substances, entering the United States via mail shipment.
- Determine the extent to which foreign health agencies are willing and able to ensure the safety of drugs being exported from their countries to the U.S.
- Assess the potential short- and long-term impacts on drug prices and prices for consumers associated with importing drugs from Canada and other countries.
- Assess the impact on drug research and development, and the associated impact on consumers and patients, if importation were permitted.
- Estimate agency resources, including additional field personnel, needed to adequately inspect the current amount of pharmaceuticals entering the country.
- Identify the liability protections, if any, that should be in place if importation is permitted for entities within the pharmaceutical distribution chain.

- Identify ways in which importation could violate U.S. and international intellectual property rights and describe the additional legal protections and agency resources that would be needed to protect those rights.

A public docket for the task force will be opened tomorrow to allow members of the public to submit comments for the record. The docket, 2004N-0115, will be available at <http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm>.

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