

Kansas Department of

# **Social and Rehabilitation Services**

Janet Schalansky, Secretary

**Long Term Care Services Task Force**  
October 23, 2003

**Pharmaceuticals from other Countries**

**Health Care Policy**  
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Good morning Chairman Bethell and members of the Committee. My name is Karen Braman and I am here to give testimony to address questions raised by the Committee regarding drugs from foreign countries, specifically Canada; if there are any efforts to allow the purchase of Canadian drugs through Medicaid; and lastly, if there are concerns about foreign drugs.

Simply stated, importation of drugs from foreign countries, including Canada, is illegal. The United States Federal Food, Drug, and Cosmetic Act (21 U.S.C. section 331), prohibits the interstate shipment (this includes importation) of unapproved new drugs. Unapproved new drugs are defined by the Food and Drug Administration (FDA) as “any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval.” Additionally, under the Act, the FDA may refuse admission to any drug that “appears” to be unapproved, placing the burden on the importer to prove that the drug sought for importation is in fact approved by the FDA.

The FDA has further stated that “opening our borders to unapproved drugs presents public health and safety concerns because it increases the risks associated with drug counterfeiting, diversion, mislabeling and improper dispensing and creates a wide channel for drugs to be transshipped into the United States without adequate regulatory oversight.”

While this is the FDA’s official position, they have allowed mail-order service under a “compassionate non-enforcement” policy to help Americans who are unable to afford the higher cost medications in America. According to a Sept. 24, 2003 Washington Post article “as many as 2 million Americans now purchase prescription drugs illegally outside the United States, but the FDA has done little to stop individuals and nonprofit groups from buying drugs in Canada and Europe, where savings range from 30 percent to 75 percent.”

According to the FDA, the Canadian government has stated that while they can assure the safety of drugs purchased legally in Canada, they cannot assure the safety of drugs transshipped through Canada or exported to the United States.

The FDA has been contradictory in its messages concerning the safety of Canadian drugs, citing that imported medications do not meet U.S. standards and refusing to permit state and local governments to import prescription drugs, while at the same time, they have looked the other way as individuals in the U.S. cross the border or send away to purchase their prescriptions from Canada.

Several states, including Illinois, Iowa, and Minnesota, recently announced that they are exploring the possibility of purchasing prescription drugs for state employees and retirees through Canada. Because it is not legal, there are currently no efforts underway to purchase medications for Medicaid beneficiaries through Canada.

I would be happy to stand for any questions.