



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

August 20, 2004

Via Fax: (202) 727-0505

The Honorable Anthony Williams
John A. Wilson Building
1350 Pennsylvania Avenue, NW
Washington, D.C. 20004

Dear Mayor Williams:

I write to express our dismay that the government of the nation's capital would initiate a program to import prescription drugs from Canada, in violation of longstanding drug laws administered by the U.S. Food and Drug Administration. The safety of our prescription drug supply is an important responsibility of public officials, and we greatly fear that your actions undermine protections that have served our citizens well.

As you may know, sixty-five years ago, Congress enacted the Food, Drug and Cosmetic Act to safeguard the public against dangerous pharmaceuticals. We here at the FDA, many of whom are your constituents, are proud that we carry out that mission in such a way that Americans have the world's safest and most effective drug supply. In recent years, however, many Americans have been anxious to look abroad to find more affordable drugs. Access to affordable drugs is one of FDA's goals as well, and we have worked very hard to approve inexpensive generic versions of brand-name drugs as soon as the original drug's patent has expired. But sending our citizens to foreign sources for drugs that are not regulated by the FDA could, in our opinion, be a serious case of "penny-wise and pound-foolish."

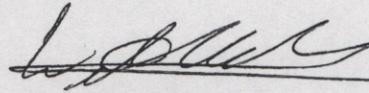
Your internet link to the state of Minnesota's "Minnesota RXConnect" website utilizes another state's judgment to guide citizens of the District of Columbia in purchasing drugs from Canadian pharmacies. Please understand that FDA has serious concerns about the Minnesota program and a similar program in Wisconsin. In Minnesota, the governor dispatched state pharmacists to inspect a number of Canadian drug stores for adherence to good pharmacy practices. Those pharmacists discovered deficiencies in all of the pharmacies they inspected in Canada, and found also that each of the pharmacies proposed to send unapproved drugs into the U.S. Minnesota nevertheless "listed" three such pharmacies as having been acceptable to recommend to Minnesotans. Some weeks later, the state of Wisconsin created a similar website listing the same three Alberta, British Columbia, and Manitoba pharmacies. Wisconsin also entered into formal written

agreements that were intended to govern the practices of those pharmacies (e.g., that the pharmacies would not sell generic drugs that are cheaper in the U.S. or drugs that should not be shipped by mail). Unfortunately, Wisconsin's experience has been one of repeated violations of their agreement, disregard for specific promises, and repeated sale to Wisconsin citizens of drugs of dubious quality.

Lastly, I must express doubts that you or any other public leader will be able to do a better job of ensuring that Canadian pharmacies send only safe and high quality drugs to your constituents, when Minnesota and Wisconsin have been unable to do so. Moreover, I refer you to the attached letters to Minnesota Governor Tim Pawlenty and Wisconsin Governor Jim Doyle, that provides more detail about FDA's considerable concerns about importing foreign drugs.

I hope that our concerns will give you pause about the District's program, and would be happy to meet with you or your staff at your convenience to further discuss our numerous concerns about drug importation.

Sincerely,

A handwritten signature in black ink, appearing to read "W. K. Hubbard", written over a horizontal line.

William K. Hubbard
Associate Commissioner for Policy and Planning

Enclosures