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Department of Health and Human Services

Public Health Service  
Food and Drug Administration  
Rockville MD 20857

May 24, 2004

Via Fax: (312)814-6183

The Honorable Tim Pawlenty  
The Governor of Minnesota  
Office of the Governor  
130 State Capitol  
75 Rev. Dr. Martin Luther King Jr. Blvd.  
St. Paul, Minnesota 55155

Dear Governor Pawlenty:

I write to express our continued concerns at your efforts to encourage the importation of foreign drugs that have not been shown to be safe and effective for sale in the United States. We informed you in February that the launching of your "Minnesota RxConnect" website represented an endorsement of the practice of importing foreign unapproved drugs – drugs for which FDA cannot assure the American public of their safety, effectiveness or quality. Your recent decision to encourage state employees to purchase Canadian drugs from pharmacies not licensed in the United States is a further indication of your willingness to risk consumer safety in the name of affordability. We continue to believe there are far better approaches to providing more affordable, safe and effective medications to your constituents without compromising their safety or the integrity of the U.S. drug supply.

We believe your proposal of eliminating "co-pays" for state employees buying foreign unapproved drugs is irresponsible because it encourages your citizens to seek medications from outside the safety net provided by U.S. drug laws designed to assure consumer safety. While I understand that Minnesota sent inspectors on pre-announced visits to Canada to "inspect" the Canadian pharmacies that would dispense these drugs, it has become apparent that your inspectors found numerous deficiencies in those pharmacies, refused to certify the vast majority, and had doubts even about the few that you ultimately accepted for your Minnesota RxConnect program. We also understand that Minnesota inspectors conducted additional inspections beyond the first round and request that you share with us the results of these additional inspections. Notwithstanding the findings from the pharmacy inspections, at this time, the Food and Drug Administration cannot make any affirmative statements about the source, safety, or legality of drugs from those pharmacies.

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in any European country can be freely sold to another. Thus, an expansion of your efforts to Europe will, as a practical matter, be exposing your citizens to medicine produced and sold in many countries.

Lastly, the National Association of Boards of Pharmacy has proposed a possible program under which NABP would send trained pharmacy inspectors to Canadian pharmacies to determine if those pharmacies meet established pharmacy practices in the United States. As you know, such a program does not currently exist and most pharmacy professionals believe that, without some sort of pharmacy certification program, drug quality problems are inevitable. I would like to ask if you agree with NABP's proposal and whether you would be willing to work with NABP on this proposal. While it won't alleviate the Agency's concerns about the quality and safety of foreign drugs, it would provide a basis for assuring foreign pharmacies meet some minimum standards.

As mentioned in our earlier meeting and correspondence, we understand your desire to give your constituents access to more affordable medications, and we share that goal with you. However, doing so in ways that place citizens at risk is not the answer, in our view, and we urge you to recognize that risk and act responsibly to address it.

Sincerely,

William K. Hubbard  
Associate Commissioner for Policy  
and Planning

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