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CHICAGO, ILLINOIS 60601

ROD BLAGOJEVICH  
GOVERNOR

December 22, 2003

The Honorable Tommy Thompson  
Secretary  
United States Department of Health & Human Services  
200 Independence Avenue, S.W.  
Washington, DC 20201

Dear Secretary Thompson:

As you are aware, I have been working for several months to find ways to help the people of Illinois save money on the high cost of prescription drugs. I was encouraged by your recent statements regarding your willingness to approve a small-scale demonstration project around the issue of reimportation of prescription drugs from Canada. We would like to work with you to design an effective pilot program that complies with the law. I am writing today to request your authorization for the State of Illinois to launch the first reimportation demonstration program.

As Justice Brandeis eloquently articulated in 1932, "[i]t is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments." Few know the wisdom of this tenet better than you. As the Governor of Wisconsin, you responded to a crisis of escalating welfare costs by creating an innovative welfare to work program, and effectively lobbied Washington to allow its implementation, despite apparent conflicts with federal law.

All told, under your stewardship, the State of Wisconsin obtained over 75 waivers for purposes of implementing experimental programs in the welfare arena. Your innovation in Wisconsin's approach to welfare reform demonstrates that when given the chance to do so, states can often successfully use their own ideas to meet the major challenges of the day. That kind of innovation is clearly needed when it comes to bringing down the price of prescription drugs.

Last year, Illinois spent over \$340 million on prescription drugs for its 230,000 employees and retirees, and a total of \$1.8 billion on prescription drugs for all of the

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state's health programs combined. With the cost of prescription drugs continuing to soar, this year, we'll spend even more.

Citizens in Illinois, and across the nation, pay 30-80% more for many of the same prescription drugs sold in Canada. In the face of a state fiscal crisis, an economy that continues to falter, and the ever-increasing cost of prescription drugs, as Governor, I have no choice but to explore different options that can help the consumers and taxpayers of Illinois.

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("the Act"), Congress has granted you the power, and authorized the necessary appropriations, to permit Illinois' implementation of the first reimportation pilot program. First, you could certify to Congress, under Section 804, subsection (l), of the Act that for the narrow purposes of Illinois' pilot program, reimportation poses no additional risk to the public's health and safety, and would result in a significant reduction in the cost of prescription drugs to consumers. You may then utilize the authority Congress granted you under section (j) of the Act, which authorizes you to grant waivers of the prohibition on reimportation, to grant Illinois a waiver authorizing the reimportation of an agreed list of prescription drugs. Additionally, because Congress authorized the appropriation of such funds as are necessary to oversee any reimportation program, funding concerns should not bar your consideration of our request.

With your approval, we will work with your staff and the FDA to implement a pilot reimportation program. The principle tenets and requisite safeguards of our proposal are as follows:

1. The State of Illinois, Office of Special Advocates for Prescription Drugs, in conjunction with the FDA, will develop a preferred drug list, detailing those drugs that can be safely obtained from Canadian sources.
  - a. The list will be comprised of predominately brand-name drugs for long-term usage.
  - b. Only drugs that can be obtained more cost-effectively from Canada than from the United States will be included.
  - c. The list will be periodically updated to ensure continued cost-savings.
  - d. Only FDA-approved drugs in FDA-approved dosages will be eligible for inclusion on the list.
2. The State will implement the following additional protections to ensure patient safety.
  - a. No first-fill. Plan participants must first have an eligible prescription filled by an Illinois pharmacy with a 30-day supply before obtaining a refill for that drug through the importation program.
  - b. Illinois will implement a Primary Care Pharmacist model, whereby every participant in the program would have the opportunity to choose an Illinois pharmacist to coordinate and monitor his or her drug therapy.

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- c. In collaboration with the University of Illinois College of Pharmacy, Illinois will implement a monitoring program to evaluate the safety/efficacy of drugs received by plan participants from all sources.
  - d. All drugs distributed through the program will be dispensed in manufacturer-sealed containers with child-resistant caps or an equivalent safeguard.
  - e. Illinois will contract with a private entity to maintain a toll-free number with a pharmacist available 24 hours a day, 7 days a week, to answer any medication-related questions by plan participants.
  - f. In addition to oversight by the State of Illinois, all wholesalers and pharmacies involved in filling prescriptions under the program will be licensed and regulated either by authorities in Canada or by authorities in the United States.
  - g. Prescriptions will be dispensed only pursuant to a valid prescription.
3. Reporting
- a. Illinois will periodically report to the United States Department of Health and Human Services regarding the effectiveness and cost-savings of the program.

This program, subject to your approval, could be implemented through one of two plan designs. As described in our recently-released study on this issue, Illinois could contract with a Canadian Pharmacy Benefit Manager ("PBM") to administer the program by mail-order, distributing prescriptions to patients directly from the Canadian PBM. Or, Illinois could work with Canadian sources to obtain eligible prescription drugs in bulk. The drugs would then be sent to a mail-order facility in Illinois for distribution. In both of the scenarios described, the State would stipulate performance and safety standards for facilities in Canada and in Illinois and would regularly inspect all facilities for adherence to those standards.

Finally, the program proposed by Illinois would be instituted as a pilot program, involving only a small population of participants at the outset. As described in our study, we would begin by instituting a program, on a voluntary basis, for state employees and retirees. The scope of the study would be further narrowed in its initial stages by limiting the number of eligible drugs to those agreed to by the State and the FDA. If successful, the program could later be expanded to include additional drugs and/or additional populations in Illinois.

I believe that we have a unique opportunity to test the concept of importation with the implementation of a pilot program in Illinois. Our program will allow HHS and the FDA to gauge, on a small-scale, the feasibility of drug importation, while authorizing Illinois to obtain safe, effective, and affordable prescription drugs for its employees and retirees in a controlled setting.

The State of Illinois very much wants to import prescription drugs from Canada in a way that is fully compatible with current regulations, and meets with your approval.

Designating Illinois as a demonstration project would allow us to do just that, and provide a model that other states could follow.

I would appreciate it if you could let us know whether you will authorize Illinois to launch a reimportation demonstration program within thirty days. Thank you for your consideration.

Respectfully,



Rod R. Blagojevich

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cc: Mark B. McClellan  
Office of the Commissioner  
United States Food and Drug Administration  
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Rockville, Maryland 20857