

**Office of the Special Advocate for Prescription Drugs**

**Rod R. Blagojevich, Governor**  
State of Illinois  
401 S. Clinton Street, 4<sup>th</sup> Floor  
Chicago, IL 60601

Ms. Karen Strambler  
Office of the Commissioner  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857  
[Karen.Strambler@fda.gov](mailto:Karen.Strambler@fda.gov)

VIA E-Mail

**Re: Docket No. 2004N-0115**

Dear Ms. Strambler:

On behalf of the State of Illinois we are requesting to present at the public hearing on April 14, 2004 on Docket No. 2004N-0115. Per your published notice please find the requested information below:

Presenter's names: Scott McKibbin and Ram Kamath, Pharm.D.

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Affiliation: Employees of the State of Illinois  
Title: Special Advocate For Prescription Drugs

Approximate time requested for presentation: 40 minutes

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### Summary of Presentation:

As the FDA is aware, the Office Of Special Advocate For Prescription Drugs, State of Illinois, conducted a feasibility study on the issue of reimporting prescription drugs from Canadian sources for State employees and retirees. Governor released this report on October 27, 2003. Our presentation will focus on the findings presented in our report along with additional first hand accounts of our fact-finding mission to Canada in October 2003. The following key findings will be discussed during our presentation:

- Pharmacy practice in Canadian provinces of Manitoba and Ontario is equal to or superior to pharmacy practice in the State of Illinois.
- Prescription medication dispensed in Canada is primarily distributed in “unit of use or stock bottles” i.e., sealed packages, shipped directly from the manufacturer. Manufacturer-sealed, packages dramatically reduce the risk of medication errors and counterfeiting.
- The provincial regulatory systems in Manitoba and Ontario provide substantially equivalent protection for the health and safety of the public as is provided for in the State of Illinois.
- Though not identical in statutory or regulatory text, both countries’ methods of ensuring safety and efficacy of prescription drugs are comparable.
- Canada’s system for the pricing and distribution of pharmaceuticals is less likely to foster drug counterfeiting than that of the system in the United States.
- The professional regulation of licensed pharmacists in the Canadian provinces visited is as rigorous as that which is in place in Illinois.
- The pharmaceutical manufacturing, storage, distribution and dispensing requirements under Canadian law are substantially equivalent to corresponding requirements under federal law in the United States.
- Several features of our proposed plan designs for State of Illinois employees and retirees would increase patient safety. These design features include:
  - No “first fill” in the mail order system. Employees and retirees would need to have been prescribed and tolerated a prescription drug for a minimum of one month in the Illinois retail system prior to utilizing the Canadian Mail Order Plan.
  - Patients would be required to submit a detailed medical history as a prerequisite to participating in the program.
  - Only a restricted list of drugs would be available.
  - “Unit of Use” (also referred to as “Stock Bottles”) packaging sealed and shipped directly from the manufacturer to the pharmacy and then to the patient will dramatically reduce patient medication errors and the possibility of counterfeit drugs.

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- The State would implement a Primary Care Pharmacist (PCPh) Model to improve patient safety. Each patient would select a PCPh who would coordinate pharmaceutical care (incorporating prescriptions obtained through local retail pharmacies, domestic mail order pharmacies, and Canadian Mail Order Plan). The State would use a portion of savings generated through the importation program to fund the PCPh Model.
- Assuming all eligible drugs were provided under the proposed Canadian Mail Order Program, total estimated net savings for 12 months of program operation would be just over \$90 million dollars.

As per the published hearing notice, please expect a PowerPoint presentation by close of business on April 7, 2004. We look forward to working with you on this important hearing. In addition to my office phone number on page one of this letter you may also reach me on my cell phone at 312-636-1939.

Respectfully Submitted,

Scott McKibbin  
Special Advocate For Prescription Drugs