



**OFFICE OF THE GOVERNOR  
CHICAGO, ILLINOIS 60601**

**ROD R. BLAGOJEVICH  
GOVERNOR**

September 19, 2006

Andrew C. von Eschenbach, M.D.  
Acting Commissioner of Food and Drugs  
U.S. Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

Dear Commissioner von Eschenbach:

Over the last several years, your predecessors and I have disagreed strongly on the issue of re-importation of prescription drugs. I have been a strong advocate for opening the global marketplace to American consumers, while the Food and Drug Administration (FDA) has consistently sided with the drug manufacturers in keeping the marketplace closed and forcing consumers to pay artificially high prices.

Today, the Auditor General of Illinois will release a report about I-SaveRx, our prescription drug re-importation program that cites my administration for facilitating the importation of prescription drugs without FDA approval. His report argues that the I-SaveRx program is in violation of federal law. It reads, "Drugs are approved for use in the United States pursuant to the provisions of federal law as stated in the Food, Drug and Cosmetic Act. Virtually every time an individual or entity imports or causes the importation of a prescription drug, they are in violation of the FD&C Act."

We respectfully disagree with the Auditor General's finding, given that the FDA has tacitly permitted more than one million Americans each year to import prescription drugs from abroad, and given that the FDA has never taken steps to prevent the I-SaveRx program from operating in Illinois, Wisconsin, Kansas, Missouri and Vermont. In fact, you and I both know that the FDA has seized and tested approximately 1% of the prescription drugs imported through I-SaveRx and has never found fault with any of the medications. We also both know that, in recent months, the FDA has increased the number of seizures of medications both for programs like I-Save Rx and other importation programs across the nation.

Please be advised that while we highly respect and very much appreciate our Auditor General's work, and while we will implement as many of his recommendations as possible, we fully intend to continue allowing the people of Illinois to purchase safe, affordable medicine from approved pharmacies in Canada, the United Kingdom, Australia and New Zealand. We will not be bullied or pressured by the FDA into choosing drug company profits ahead of the basic needs of senior citizens and the uninsured.

In addition, we are also going to move forward and expand the I-SaveRx program by making it available to state employees and dependents. Given that the State's annual costs for providing prescription drugs to employees, dependents, and others (prisoners, patients in state facilities, and others whose care is covered by the State) has increased by an average of 15% per year over the last five years, and given that employees and retirees often face brand name co-payments of \$40-80, broadening the scope of I-SaveRx will help the taxpayers save money by reducing the State's prescription drug costs. It will also help employees save money because they would no longer have to make co-payments when the medication they need is available at far less cost from pharmacies in Canada, United Kingdom, Australia or New Zealand. As we implement as many of the Auditor General's findings as possible for our program, we will keep those recommendations in mind as we expand the program to State employees, dependents and others.

The report also says that because our I-SaveRx program works with foreign pharmacies, their inspection makes it impossible to fully complete the forms used to inspect pharmacies in Illinois. Also, because pharmacies in the United Kingdom, Canada, Australia and New Zealand are governed by their own national standards, that differs from the standards in the Illinois Pharmacy Practice Act.

As you know, the standards for inspections and regulations required in each of those nations exceed those used here in the United States.

It is not surprising that the Auditor General found this, given that the forms used in Illinois include fields that are specific to United States based pharmacies (for example, requiring a Drug Enforcement Agency number). Nor is it surprising that the Illinois Pharmacy Practice Act is not identical in word and verse to the regulations of four different nations. The Auditor General finds that an out-of-state pharmacist can only dispense medication if licensed by the State of Illinois or, as a "mail order" pharmacy, be located within the United States.

Those are reasonable standards if the State of Illinois were only working with domestic pharmacies. But there is no way for a re-importation program operated on a state level to comply in every way, shape and form with rules that were written long before the concept of re-importation was developed. As a result, when one or several states acts in a way that differs from the federal government, each state participating in a non-federal re-importation program runs the risk of its Auditor General finding that the regulation of foreign pharmacies in some way differ from local regulations.

Our Auditor General also issued a finding saying that no State employee paid for with federal funds should be used to advance the I-SaveRx program in any way. If you believe that the I-SaveRx program violates federal law, as the Auditor General does, than this finding makes sense. But because the FDA refuses to publicly embrace a concept that would significantly reduce prescription drug prices for tens of millions of people, we have no choice but to act on our own and operate the program ourselves.

That includes using all of the resources of state government to make the program available to as many people as possible, including employees of the Illinois Department of Employment Security (IDES), who spend their day dealing with the unemployed – people who don't have jobs and therefore don't have health insurance or prescription drug coverage. Yes, IDES employees are federally funded. But they are also the ideal candidates to help people afford the medicine their doctor prescribes.

In addition, because the FDA refuses to permit the re-importation of prescription drugs, our request to import vaccines purchased abroad in the fall of 2004 was also denied. Our Auditor General found that we should have obtained your approval before purchasing the vaccines. When the nation was facing a shortage of 55 million does of flu vaccine and through our own devices, we were able to procure vaccines for Illinois and put several other states in a position to procure vaccines for themselves as well.

Rather than erecting every conceivable roadblock to stop the importation of the vaccines, the FDA should have thanked us for addressing the problem ourselves and immediately approved it. Instead, we faced bureaucratic hurdle and delay after bureaucratic hurdle and delay, only to ultimately be denied. Incredibly, the FDA used the excuse of oversupply as one reason to deny our application, even though it purchased vaccines from the same manufacturers as we did after they knew we already had the vaccines available.

Our Auditor General is doing his best, and while we agree with some of his recommendations and disagree with others, he is ultimately trying to audit a program that fundamentally is at odds with the approach taken by the FDA – an approach that denies consumers access to the global marketplace for prescription drugs.

When states like Illinois take on a responsibility that ought to belong to the federal government, that requires creating a complicated program that will not be in lock step with every local rule and regulation created a time before anyone envisioned the concept of re-importation of prescription drugs.

No Governor and no administration wants to incur audit findings saying that they are operating a program in violation of federal law. But when the choice is helping people afford the medicine they need or incurring audit findings, there's really no choice. Please understand that while we will do everything in our power to implement some of the Auditor General's recommendations, we will not cease operation of the I-SaveRx program.

Your decision to make Plan B available over-the-counter indicates that you are willing to look at issues in a way different from your predecessors. Hopefully you will take a look at the FDA's policy opposing re-importation of prescription drugs and recognize that a national policy that helps our citizens access the global marketplace is the better approach.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, reading "Rod Blagojevich". The signature is written in a cursive, flowing style with a large initial "R" and "B".

Rod R. Blagojevich  
Governor