IN THE HONORABLE SENATE OF THE STATE OF ILLINOIS
FOR THE NINETY-SIXTH GENERAL ASSEMBLY
SITTING AS AN IMPEACHMENT TRIBUNAL

In re	)
Impeachment of	)
Governor ROD R. BLAGOJEVICH	)

HOUSE PROSECUTOR'S
MOTION FOR ADDITIONAL DOCUMENTS OR MATERIALS

House Prosecutor David W. Ellis, pursuant to Senate Impeachment Rule 15(b)(2), moves for the admission of additional documents into evidence and, in support thereof, states as follows:

1. The House Prosecutor seeks to admit a letter from Lester Crawford, Acting Commissioner of the Food and Drug Administration, to Governor Rod R. Blagojevich at the Impeachment Trial.

2. A copy of this document is attached to this Motion.

3. This document will be introduced during the live testimony of William Holland.

4. This document is relevant and material because it demonstrates the Governor's action with regard to, and responsibility for, the I-SaveRx Program as provided in paragraph 10 of the Article of Impeachment.

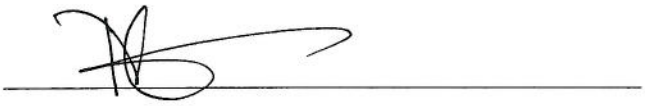
5. This document is not redundant because the full letter sent by Commissioner Crawford is not currently in evidence.

6. Moreover, although some evidence related to this issue is contained in the House impeachment record, under Senate Impeachment Rule 15(g), the evidence is not deemed redundant simply because it relates to material already in the record.

WHEREFORE, the House Prosecutor respectfully moves for the admission of a Letter from Lester Crawford, Acting Commissioner of the Food and Drug Administration, to Governor Rod R. Blagojevich into evidence at the Impeachment Trial.

Respectfully submitted,

DAVID W. ELLIS,
HOUSE PROSECUTOR



David W. Ellis
Chief Counsel to the Speaker
Illinois House of Representatives
412 State House
Springfield, IL 62706

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DEPARTMENT OF HEALTH & HUMAN SERVICES

June 3, 2004

Governor Rod R. Blagojevich
Office of the Governor
State Capitol
207 Statehouse
Springfield, Illinois 62706

Dear Governor Blagojevich:

I am writing in response to your letters to Secretary Thompson dated October 27, 2003, and December 22, 2003, regarding your efforts to find ways to help the people of Illinois save money by purchasing prescription drugs from outside the United States. In your letters, you inquire about whether the Department of Health and Human Services may approve a demonstration project for the importation of prescription drugs from Canada. Although at the Food and Drug Administration (FDA) we share your concern and urgency related to the cost and safety of prescription drugs for our citizens, we do not believe that a waiver could be granted to allow a state's pilot project for the safe importation of prescription drugs under the current law. Our rationale is described in more detail below.

Secretary Thompson has made the provision of affordable prescription drugs for seniors one of the Department's highest priorities. With assistance from Congress last year, we achieved successful passage of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), providing for a prescription drug benefit under Medicare. Pending the effective date of that benefit, the Secretary has published new rules under which immediate savings are available for seniors through a drug discount card program. Meanwhile, at FDA, I have made it a priority for the agency's medical and scientific experts to establish programs that promote access to innovative treatments designed to help Americans live healthier lives and to ensure that Americans have access to medications and treatments that they can afford.

FDA's statutory responsibility is to assure the American public that the drug supply is safe, reliable and secure. For more than 60 years, the Food, Drug, and Cosmetic Act has ensured that Americans can be confident that, when they use an FDA-approved drug, the medicine will be safe and effective and will work as intended in treating their illness. In carrying out this responsibility, FDA works to make medicines accessible and to help doctors and patients use them as effectively as possible through such steps as expanding access to generic medicines, reducing the time and cost of showing that new medicines are safe and effective, and providing up-to-date information for health professionals and patients to obtain the benefits and avoid the risks associated with powerful medicines.

Unfortunately, the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. In recent years, FDA has seen growing evidence of efforts by increasingly well-organized counterfeiters, backed by sophisticated technologies and criminal operations, intent on profiting from drug counterfeiting at the expense of American patients. The agency is doing its best to use its current authorities and resources to stop the increasing flow of violative drugs into this country, but the task is daunting. Each day, thousands of individual packages containing prescription drugs are imported illegally into the United States. FDA is working to speed the availability of anti-counterfeiting technologies, but these technologies have not yet been proven.

FDA remains concerned about the public health implications of unapproved prescription drugs from entities seeking to profit by getting around U.S. legal standards for drug safety and effectiveness. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S.-approved prescription drugs are, in fact, of unknown quality. Consumers are exposed to a number of potential risks when they purchase drugs from foreign sources or from sources that are not operated by pharmacies properly licensed under state pharmacy laws.

The agency's objections to proposals that would create large, legal channels for drugs to enter our drug supply without assurances of safety are based on concerns that they will create substantial drug safety problems without clear, large-scale, long-term benefits. The principal concern is that such proposals would weaken our existing safety protections rather than providing the necessary resources and additional authorities that would be required to enable the agency to ensure drug safety and security.

Some cities and states would like to import cheaper prescription drugs from abroad, as you have requested in your letter. However, our review indicates that such state pilot projects are not authorized under current law and present added safety concerns. First, the MMA authorized the importation of prescription drugs from Canada, but with the restriction that importation may not occur until the Secretary certifies to Congress that allowing drug importation poses no additional risk to consumers and results in significant reductions in the cost of prescription drugs. Both Secretary Thompson and Secretary Shalala prior to him (separately) have concluded in the past that such products were potentially dangerous and should not be imported. Moreover, the agency has documented large amounts of unsafe and unapproved drugs entering this country via mail shipments (the following link provides additional information about the types of unapproved products being imported into the United States: http://www.fda.gov/bbs/topics/NEWS/2004/NEW01011.html) and via Internet Web sites that often appear to be providing FDA-approved products but ultimately have been found to be fraudulently peddling unapproved drugs from various unapproved sources.

Second, last year, when Congress enacted the MMA, it directed the Department to conduct a comprehensive study and prepare a report to Congress on whether and how importation could be accomplished in a manner that ensures safety. Given that the MMA

gives the Department 12 months to complete that report, Congress clearly envisioned that the Department could also take a least a year to evaluate the public health risk and cost-saving conditions set forth in the certification standard. The Department is currently working on the comprehensive report and has created an intergovernmental task force to steer this effort to completion by the Congressional deadline this year. Thank you for sending representatives from Illinois to participate in the public meeting of the task force; their input was greatly valued and appreciated.

Third, the MMA does not authorize any specific waivers, state pilot programs, experiments, or other temporary or short-term programs for importing unapproved drugs. In essence, the Secretary must certify that unapproved drugs can or cannot be safely imported for all Americans not just those people in one state or region of the country.

Fourth, FDA senior staff discussed the proposed Illinois pilot program with your representatives and gave them an analysis that detailed a number of safety concerns, legal concerns, unanswered questions, and questions about the program's benefit. We believe it is important for you to continue to try and address these questions.

Finally, the agency is already aware of concerns with state programs that are utilizing state-sponsored Web sites to facilitate importation of drugs by state residents. These transactions are very often in contravention of state pharmacy laws and have been found to pose substantial safety concerns. In Wisconsin, where the state operates such a Web site, just recently State health officials were required to warn Canadian pharmacies to cease and desist from supplying unapproved drugs to Wisconsin residents who used the state Web site to facilitate a purchase, but then received unapproved products that they did not request. In Minnesota, representatives from the Minnesota Board of Pharmacy traveled to Canada to identify Canadian pharmacies that the state could commend to Minnesota citizens via a state-sponsored Web site, but upon inspection, found that the vast majority of the Canadian cross-border pharmacies that were visited had significant safety problems and other deficiencies. Also, both Minnesota and Wisconsin have expressly disclaimed any liability or responsibility for these foreign pharmacies and thus have left their consumers with only a "buyer beware" option that is inconsistent with U.S. drug laws.

FDA firmly believes that it can do even more to make safe and innovative drugs more affordable in the United States, but to succeed, we need to find safe and affordable solutions that, when implemented, do not put consumers at risk. FDA appreciates and supports your commitment to making drugs more affordable for seniors and other consumers, and there are several safe and legal approaches that we would be happy to explore further with you. But we must be cautious and deliberate when considering proposals to accomplish this goal to ensure that any changes do not require American

citizens to give up the "gold standard" in drug safety that has become a hallmark in this country. I am confident we can work cooperatively towards solutions that will not be a disservice to the American people.

Sincerely,

Lester M. Crawford, D.V.M., Ph.D.
Acting Commissioner of Food and Drugs