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Richard H. Carmona, M.D., M.P.H., F.A.C.S.
VADM, USPHS
United States Surgeon General
Chairman, HHS Task Force on Drug Importation
Office of the Surgeon General
Rockville, MD 20857

Dear Dr. Carmona:

Thank you for inviting the National Association of Attorneys General ("NAAG") to present information to the members of the U.S. Department of Health and Human Services' Task Force on Drug Importation. I appear before you in my capacity as Attorney General for the State of Maine, as a member of NAAG, and as a co-chair of NAAG's Pharmaceutical Pricing Task Force. While I know that many of my fellow State Attorneys General share my views regarding drug importation, I want to make clear that I am not presenting testimony on behalf of the entire NAAG membership. Nor am I presenting testimony on behalf of all members of NAAG's Pharmaceutical Pricing Task Force.

State attorneys general are responsible for protecting the public and enforcing the laws of our states. We advise various state agencies with respect to compliance with state and federal laws. We also advise various state licensing boards such as pharmacy and medical boards. During the past few years, we have been advising state legislatures and executive agencies regarding legislation designed to increase the affordability of, and access to, prescription drugs for our citizens. My state, Maine, has been particularly active in this regard.

The United States represents the largest pharmaceutical market in the world. Yet, we pay the highest prices in the world for pharmaceuticals. These prices have strained our federal, state and municipal budgets and have made it impossible for many of our citizens to access the prescription drugs that their physicians prescribe. The result is that people are becoming more ill, requiring more institutionalized care and dying sooner than they should.

I know you are aware that a number of congressional, state and local governmental websites provide information designed to assist consumers with purchasing prescription drugs from Canadian pharmacies. You also are aware that a number of municipal and state health care plans are attempting to implement prescription drug purchasing programs utilizing drugs imported from Canada. These actions by governmental officials appear to directly contradict the FDA's official position that importation is illegal. Similarly, the actual experience of millions of Americans who have safely imported prescription drugs from Canadian pharmacies appears to directly contradict the FDA's repeated warnings that importation poses a threat to the safety of Americans. As a law enforcement and public safety official, I am conflicted. On the one hand, I don't want to encourage citizens to violate federal law. On the other hand, however, for many, the only way to access the health-sustaining drugs that they need is to apparently violate federal law.

Due to high drug prices in Maine, thousands of our citizens have been importing prescription drugs from Canadian pharmacies over the past few years. A number of these individuals have looked me squarely in the eye and told me that purchasing from Canadian pharmacies was the only way they could have afforded the drugs that their physicians prescribed. These imported drugs were primarily maintenance drugs for chronic conditions such as arthritis, diabetes, hypertension, heart disease and elevated cholesterol. The majority of the drugs purchased were brand named drugs.

The differentials in costs in the United States and Canada are substantial. Citizens in this country pay 30 to 75 percent more than Canadians do for the same drugs. On a recent bus trip to St. Stephen, New Brunswick, nineteen Mainers collectively saved almost \$20,000 for a six month supply of drugs. This is typical of the experiences of other Maine citizens who have purchased drugs from Canadian pharmacies either in person, through the mail or over the internet.

For a growing number of people in Maine, the choice is to either purchase drugs from a Canadian pharmacy or do without. The consequences of electing the "do without" option often involve worsening health, eventual institutionalization and death. These consequences often mean increased costs to the State, costs that could have been avoided had the individual stayed on the prescribed maintenance drug. I am not exaggerating to make a political point. I am stating a fact.

I continue to be dumfounded by FDA officials' intransigent attitude toward importation. Like these federal officials, I care greatly about patient safety. I certainly want to ensure that citizens in my state access drugs that are safe. However, I believe that procedures exist to ensure that consumers are protected from unsafe drugs.

Twenty attorneys general recently described such a procedure in a letter to Secretary Thompson. It involves allowing the states to be appointed as licensed wholesalers or to contract with licensed wholesalers for the importation of FDA approved prescription drugs from Canada. The licensed wholesalers could contract directly with

licensed Canadian pharmacies which would be required to meet safety standards set by the health departments of the individual states. All prescription drug shipments could be made directly to the states. The states would work with Health Canada and the FDA, both of whom have systems to ensure the safety and quality of prescription drugs, to inspect Canadian pharmacies and exchange drug plant inspection information.

All drugs would be manufactured in FDA approved facilities and imported into the United States from Canada in their original packaging. All drugs would be tracked using advanced counterfeiting technologies such as radio frequency identification, chemical markers and barcodes. In addition, steps would be taken to ensure that the FDA's tracking system works in conjunction with Canada's own comprehensive labeling system, which includes the issuance of a unique drug identification number for all prescription drugs that are commercially sold within Canada.

States are sovereign entities that negotiate for billions of dollars worth of medical goods and services for our state agencies and health plans. Our pharmacy boards already regulate pharmacists and prescription drug wholesalers. In some states, we administer our own prescription drug discount programs. With the assistance of the FDA, I am certain that we could work with Canadian authorities to develop a process for the safe importation of prescription drugs.

Please note that I have emphasized Canada here because I believe that we should start with Canada and later expand the program to other countries. I am aware that the Canadian market is small compared to that of the United States and that Canadian importation is not the long term answer to provide sustained price relief for American consumers. However, relief is urgently needed now and importation will provide that immediate relief.

Let me say that I also support certain efforts ongoing in the federal Congress that are intended to provide prescription drug price relief by allowing for importation from Canada with certain restrictions. I particularly support the Pharmaceutical Market Access and Drug Safety Act of 2004, which is sponsored by Senators Dorgan, Snowe, Kennedy, Daschle and McCain among others. This bill includes specific measures to ensure the overall safety and integrity of imported drugs by requiring that a chain of custody be maintained and inspected. It requires that wholesalers meet high standards – including detailed record keeping, labeling, and tracking requirements. It requires frequent FDA inspections of pharmacies and wholesalers. And it employs the latest in anti-counterfeiting technologies.

In closing, let me say that I appreciate the complexity of the product safety issues that you are dealing with – including risks of counterfeiting, contamination, and mislabeling. I also appreciate the politically charged atmosphere that surrounds the drug importation issue. I believe the key to whether you will be able to recommend to Secretary Thompson that prescription drug importation can be conducted safely is whether you want to or not. I came here today in the hope that you indeed do want to. I came here in the hope that you are working to protect the consumer, rather than the

pharmaceutical industry. I certainly hope that I am right. Thank you for your attention and I wish you well with your work.

Sincerely,

A handwritten signature in black ink, appearing to read "G. Steven Rowe". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

G. Steven Rowe
Attorney General