DEC 21 2004

The Honorable J. Dennis Hastert
Speaker
United States House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

President Bush has been proud to work with you and other Members of Congress to pass important legislation addressing the high cost of prescription drugs. Most significantly, the President worked with Congress to pass the landmark Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108-173, which will make prescription drug coverage available to every senior in 2006. Already, an estimated 5.8 million seniors are saving hundreds – and in some cases, thousands – of dollars through Medicare-approved drug discount cards.

We also worked with you to lower drug costs for millions of Americans by strengthening competition between generic medications and brand-name drugs. That measure will save Americans more than $35 billion in drug costs over 10 years. And the President continues to work with you and other Members to further address the high cost of prescription drugs by passing medical liability reform.

As part of the MMA, Congress asked the Department of Commerce to examine foreign government practices affecting prescription drug prices. The enclosed report, "Foreign Drug Price Controls: Their Effects on R&D, Innovation and Consumer Welfare" ("Commerce Study"), responds to that request. Consistent with prior reports, the Commerce Study finds that government price controls and similar practices in certain foreign countries have significantly reduced returns from prescription drug sales below that which would be expected in more competitive markets. It clearly shows that these practices have the effect of reducing research and development and consequently have a negative effect on innovation and consumer welfare. The Commerce Study further demonstrates that these practices also inhibit the development of competitive markets for generic medicines, thereby denying consumers in those markets benefits, including lower prices that Americans obtain as result of competition between generic and brand-name drugs. In fact, U.S. consumers would pay, on average, 50 percent more for their generic medications if they bought them abroad.

Congress also tasked the Department of Health and Human Services (HHS) with examining issues related to importation. Importation proposals, as you know, present significant safety concerns. The system of drug regulation in this country is the strongest in the world. The

President has made clear that he would only support importation of prescription drugs if it can be done without compromising the safety of U.S. consumers.

A special Task Force chaired by the U.S. Surgeon General has examined the relevant data and considered testimony from members of the public and health experts and has now completed the enclosed "Report on Prescription Drug Importation" ("Task Force Report.") This Task Force Report makes clear that there are very significant safety and economic issues that must be addressed before importation of prescription drugs is permitted. While it is not possible to outline an exhaustive list of concerns here, any plan to permit importation must be limited to commercial importation of a discrete number of high-volume, high-cost prescription drugs from a country with equivalent drug safety protections. These drugs must have the same level of safety and effectiveness as FDA-approved products.

Consistent with the specific issues identified in the Task Force Report, any importation program must address the following:

- Integrity of the distribution system must be ensured by, among other measures, requiring drug pedigrees with adequate documentation, limiting ports of entry and distribution channels, and allowing commercial importation only from licensed foreign wholesalers to authorized sellers in the U.S. The program must exclude personal shipments via the mail and courier services. Indeed, regulating personal importation could be extraordinarily costly, on the order of $3 billion a year based on estimates of the current volume.
- Any program must limit importation to those prescription drugs most likely to yield savings – namely high-volume products for which a U.S.-approved generic is not available – and allow importation only from countries for which we have a high degree of confidence in the comparability of their drug regulatory systems. In the Administration's view, Canada is the only country from which importation should be considered at this point. Congress should also exclude drugs or classes of drugs that pose increased safety risks in the context of importation, such as controlled substances and drugs that require refrigeration during shipping;
- Any program must require that imported prescription drugs be dispensed pursuant to a valid U.S. prescription pursuant to advice from a trusted medical professional;
- Measures must be included to ensure that any purchasers of imported drugs are given full and adequate information regarding, among other things, the source of the drugs, and that packaging and labels on imported drugs meet all FDA requirements;
- Any importation program must ensure effective oversight and adequate government resources to protect American consumers;
- Any program must include the ability to use streamlined inspection procedures, and ensure appropriate remedial steps can be taken in the event of adverse events from imported drugs; and
- Any program must avoid anti-competitive provisions such as so-called "forced sale" provisions and other types of price controls.

If Congress were to pass legislation that did not address the serious safety concerns identified in the Task Force Report, or if Congress were to pass legislation that discouraged innovation or

stifled competition with provisions such as those cited above, the President's senior advisors would recommend a veto.

The Task Force Report concludes that any safe system of importation will likely produce only modest savings on the national level. The small quantity of available drugs to import results in little aggregate cost savings, and intermediaries reap much of the benefit. To address the high cost of prescription drugs more meaningfully, Congress should take steps to address the cost of excessive litigation.

The Administration looks forward to continuing to work with you to effectively address the high costs of health care and to ensure that America's consumers continue to have access to the highest quality health care in the world.

Sincerely,

Tommy G. Thompson
Secretary

Donald L. Evans
Secretary

CC: Mr. DeLay
Ms. Pelosi
Mr. Barton
Mr. Dingell
Mr. Thomas
Mr. Rangel

Enclosures

IDENTICAL LETTER SENT TO:

The Honorable William H. Frist, M.D.
Majority Leader
United States Senate

cc: Senator Reid
Senator Enzi
Senator Kennedy
Senator Grassley
Senator Baucus