EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503

July 23, 2003
(House Rules)

STATEMENT OF ADMINISTRATION POLICY

(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)

H.R. 2427 - Pharmaceutical Market Access Act of 2003

(Rep. Gutknecht (R) MN and 46 cosponsors)

The Administration strongly opposes H.R. 2427, which would waive existing health and safety standards with regard to prescription drugs imported from foreign sources without adequate assurances that such products are safe and effective. The overall quality of drug products that consumers purchase from licensed pharmacies in the United States is the highest in the world and Americans can be confident that the drugs they use are safe and effective. Unfortunately, H.R. 2427 would create serious drug safety problems. The bill would open new channels for the importation of drugs into the United States without a workable system of oversight and enforcement, allowing counterfeit, adulterated, inactive, and unapproved drugs to enter the country. These products are potentially injurious to public health and pose a threat to the security of our Nation's drug supply. H.R. 2427 would take unprecedented steps to restrict the Food and Drug Administration's (FDA) authority to assure the safety of prescription drug products to be used by U.S. consumers. It would remove the existing requirement that the Secretary of Health and Human Services assure the safety of prescription drug products prior to authorizing their importation and repeal FDA's current authority to issue rules to control importation that would be necessary to "protect the public health."

The Administration is greatly concerned for senior citizens and other patients who have difficulty paying for their prescription drugs and will work with Congress on issues of affordability. Working together, the Administration and Congress are nearing enactment of landmark legislation to provide a Medicare prescription drug benefit that will enable millions of America's seniors to receive coverage for their drugs. In addition, FDA has taken a number of significant steps to provide greater access to affordable prescription drugs that are safe and effective. These steps include new initiatives to reduce the cost of developing innovative new drug therapies and changes in regulations to speed access to more affordable generic drugs.

H.R. 2427 is dangerous legislation. It would expose Americans to greater potential risk of harm from unsafe or ineffective drugs, would be extremely costly to implement, and would overwhelm FDA's already heavily burdened regulatory system.

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