

## Personal Importation:Time for Congress, Administration to pass legislation on behalf of American patients

Letters to HHS Secretary seeking executive action on 2003 legislation have good intentions, but time for Congress to act to lower prescription prices

ST. LOUIS, MO, USA, February 28, 2017 /EINPresswire.com/ -- The publisher of <u>RxforAmericanHealth</u> and <u>AmericanRxBillofRights</u> says that while a recent letter from Senators Amy Klobuchar (D-MN), Charles Grassley (R-IA) and John McCain (R-AZ) to Health and Human Services(HHS) Secretary Tom Price asking him to utilize legislation crafted 14 years ago to exercise his authority to 'enable' personal importation



of prescription medicines under provisions of the Medicare Prescription Drug Improvement and Modernization Act of 2003, is 'admirable', it reflects the fact of the failure of Congress to overcome the opposition of Pharma, which views personal importation as a threat to its ability to impose the highest prescription drug prices in the world upon American patients.

Daniel Hines noted that "The Senators are not alone in making such a request. A group of 33 Democrat members of the House of Representatives sent a similar appeal to President Obama, asking him to issue an executive order shortly before the end of his Presidency."

"Also, throughout the last 14 years, advocates for personal importation, including me, have challenged previous HHS Secretaries to act on specific portions of the legislation," Hines says.

"The significant portions are that Congress directed that: 'The Secretary, in consultation with appropriate government agencies, shall conduct a study on the importation of drugs into the United States pursuant to section 804 of the Federal Food, Drug, and Cosmetic Act (as added by section 1121 of this Act). Not later than 12 months after the date of the enactment of this Act, the Secretary shall submit to the appropriate committees of the Congress a report providing the findings of such study' and, '…In particular, the Secretary shall by regulation grant individuals a waiver to permit individuals to import into the United States a prescription drug that—(A) is imported from a licensed pharmacy for personal use by an individual, not for resale, in quantities that do not exceed a 90-day supply; (B) is accompanied by a copy of a valid prescription; C) is imported from Canada, from a seller registered with the Secretary; '(D) is a prescription drug approved by the Secretary under chapter V' ".

Hines says these provisions are an early indication of the fact that there was-and remains today-a

realization by Congress that even in 2003, relief was needed for the millions of Americans who were then—and today—denied access to safe, affordable brand-name prescription medicines from licensed, registered pharmacies in Tier One Countries whose standards of safety and efficacy meet or exceed those of the U.S.

"Significantly, although the HHS Secretaries over the years chose not to act on the legislation, American patients acted on their own initiative, and by so doing have provided a de facto validation of the authenticity, efficacy, and validity of personal importation of brand-name medicines from Tier One Countries of which Canada is one" Hines continues.

But, he says that it is now time for Congress to enact legislation that meets the current needs of American patients.

"New legislation is needed because there exists the potential that one provision of the 2003 Act—a role for wholesalers and pharmacies-- that is not only unnecessary but could be actually harmful to the health and well-being of American patients, increase prices and establish a framework to give price control to a new entity of wholesalers and pharmacies.

"A provision in the 2003 act would empower the HHS Secretary to establish wholesale operations within the U.S., solely for the importation of medicines from Canada to be resold in the U.S., as well as allowing specific pharmacies to engage in personal importation," he explains.

"This was opposed by many proponents of personal importation when it was first presented in the 2003 legislation."

He cites several reasons for concern about this segment of the 14-year-old bill:

One of the debates that arose about personal importation from Canada in 2003, was a reaction from some Canadian officials being fearful that Canada would become 'America's drugstore' a concern that can be directly linked to the wholesaling provision;

• Equally pertinent, many American advocates of personal importation believed then, and continue to do so today, that to grant such blanket authority to wholesalers and pharmacies would defeat the very purpose of personal importation, i.e., individual American patients' access to safe, affordable brand-name medicines;

• And, he says we must be concerned about U.S. wholesalers gaining control over large supplies or sources of lower-cost medicines, giving them a capability to control prices in a manner similar to the abusive practices of Pharma, thereby crippling the ability of Americans to make purchases of their 'imported' meds from any source other than wholesalers and pharmacists.

"That's why it is time for Congress, especially those erstwhile supporters of personal importation to come together to form a consensus on comprehensive legislation for personal importation of prescription medicines as the only readily available avenue with which to ensure that no American is denied their access to vital lifeline medicines because they are unaffordable" Hines contends.

"This calls for <u>consensus building</u> in which Representatives and Senators of both parties who support personal importation who should instruct their staffs to come together to identify what opportunities—and obstacles—face enactment of new, current legislation to lower prescription drug prices via personal importation; address such problems such as one in 10 Americans not being able to afford their medicines; and, to restrain the Food and Drug Administration from the seizure and destruction of medicines which can easily be identified as authentic, safe medicines.

"By acting in such a manner to meet their obligations to the American public, Congress can develop legislation in which personal importation will have a major role and will reflect the realities of the needs of Americans patients today, rather than simply appealing for the HHS Secretary to carry the water on this issue," Hines concludes.

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