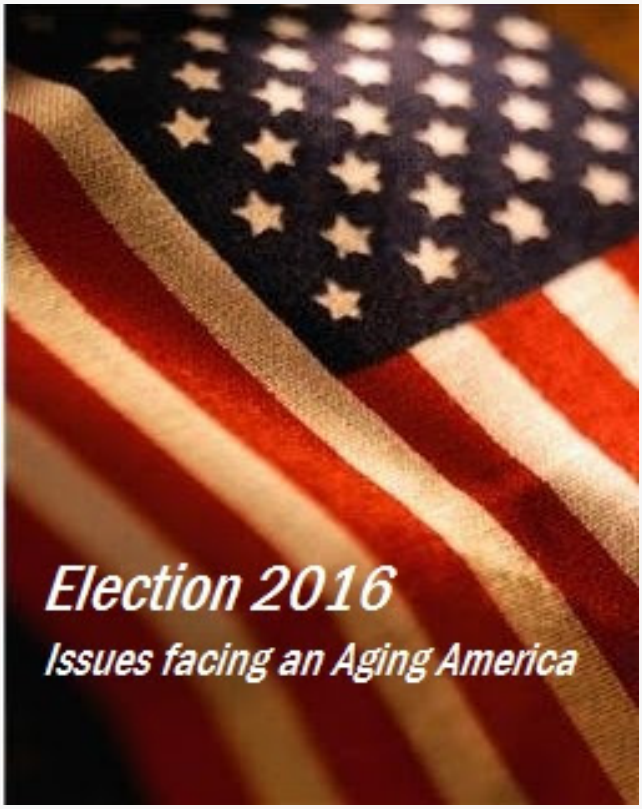
FDA, Pharma misled American Public on the ability to ascertain authenticity and safety of personally imported medicines

Candidate call for temporary importation of meds proves FDA can and should work to review personally imported brand-name prescriptions from Tier One Countries



American Flag for 2016 elections

ST. LOUIS, MISSOURI, USA, September 7, 2016 /EINPresswire.com/ -- The publisher of RxforAmericanHealth says Hillary Clinton's plans to lower prescription prices proves that the Food and Drug Administration, Pharma and Pharma supporters have misled the American Public about the ability to ascertain authenticity and safety of personally imported medicines!

Daniel Hines notes that Ms. Clinton's plan calls for importing medicines when drug prices are 'threatening' the health of Americans because the drugs are unaffordable..

"This should be extended to unaffordable 'maintenance' brand-name drugs that millions of Americans rely upon as a vital health link," Hines says.

He suggests that while her plan calls for 'temporary' personal importation, she likely would have to use executive orders to implement 'temporary 'importation because of Congress' failure to even vote on bills allowing personal importation of brand-name medicines from licensed, registered pharmacies in Tier One Countries.

"Congress should end its seemingly endless delays, investigations, statements, and business as usual," Hines says.

As to being able to validate the safety and authenticity of imported medicines which the FDA and Pharma have said is not possible, Hines notes that:

• The Clinton stance clearly relies upon medicines from what can only be construed at Tier One Countries with proven standards of safety and efficacy;

• She points out that the FDA has previously allowed such 'emergency' importation;

• This illustrates that, contrary to repeated claims of the Food and Drug Administration regarding personal importation that :

o It is possible to monitor and certify the safety, authenticity of brand name medicines 'imported' to the U.S.;

o Since such 'importation' would have to be implemented quickly to be of benefit indicates that the FDA is capable of validating the sourcing, manufacture, packaging, safety and efficacy of such medicines. It has for years cooperated with foreign sources for ingredients' oversight, and has

certainly worked with regulatory agencies in other countries during previous ‘emergency’ importation;
o The implementation of ‘temporary importation’ is proof of the safety and efficacy of imported medicines as well as their immediate economic benefit, and, their favorable impact upon Americans’ health.
o The lie to claims by Pharma and the FDA that a medicine allowed to be imported from a Tier One Country cannot be validated would be repudiated.

“A medicine that is imported in an ‘emergency’ situation that is safe and authentic does not become fraudulent after the ‘emergency’ is over, Hines says.
“When a medicine—any medicine—is unaffordable, it is unavailable, and that unavailability creates a health crisis for the individual denied access to vital medicines.”
Hines explains that a ‘temporary importation’ would illustrate the contradiction of a policy that raises questions about the ‘legality’ of personal importation, since it clearly shows that the Federal Government is willing to consider importation as a part of a national policy to lower prescription drug costs to protect the health of Americans;
“It is time that that recognition of the potential benefit to fair pricing of medicines and the right to importation should be extended to the millions of Americans who are unable to afford not only their specialty medicines, but their highly important maintenance medicines that have been proven in the Rand study of enrollees in the Affordable Care Act to improve patient health and lower drug spending”
Hines notes that the Clinton plan calls for consumer involvement and representation in an oversight group to monitor and determine when price abuses by Pharma have occurred, one of the key articles of the American Rx Bill of Rights.
He explains however that the key to the effectiveness of such a group will be based on a determination of the members of the ‘consumer’ advocacy segment and how they will be selected.
“The concept is a valid approach, but only if implemented in such a fashion as to include truly representative advocacy groups that represent patients’ rights and needs,” he notes.
He also says that the strong emphasis in the Clinton plan on the role of generics may be misplaced.
“In what is can only be construed as an admission of the failure of reliance upon generics to lower drug costs because of their being co-opted for many of the price increases in the past 18 months, the Clinton place calls for fines and penalties to be assessed against Pharma and generic industry firms that are found to profit from excessive price increases,” Hines says.
He lauds the plan calling for an end to several key elements of Pharma strategies: One is ending pay-to-delay, a tactic to delay the introduction of generics to replace brand-name drugs scheduled to lose patent protection; another is a call for negotiating Medicare Drug prices; The plan would also call for an end to the backlog of generic applications awaiting approval at the FDA; and, in one of the most dramatic recommendations, it calls for an end to direct-to-consumer (DTC) advertising by Pharma, with the money spent on DTC being redirected to Research and Development.
Hines says that Pharma has, because of its extensive lobbying and financial support of candidates at the state and Federal levels, been able to turn aside any effort to erode its ability to engage in a ‘what the traffic will bear’ pricing approach.
“ If any strategy—be it that of Ms. Clinton or Candidate Trump—is to succeed in lowering prescription drug prices, both candidates would be well-served to remember that years ago, at a press conference after a Pfizer Board meeting, then-CEO Henry McKinnell commenting on remarks by Minnesota Governor Tim Pawlenty said that efforts to lower prescription prices were nothing more than “a Prairie Fire that breaks about every four years as an election issue and then burns out.”
“It is time to end the pricing abuses of Pharma and to implement policies that will lead to the health benefits that only access to safe, affordable prescription medicines can provide. Failure to do so will once relegate the rights of Americans to enjoy the benefits of good health such access can provide in the ‘ashes of yet another Prairie Fire.’

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