HHS, NIH must define standards for ‘march-in’ implementation to help lower drug prices as part of comprehensive policy

Congressional calls for'march-in' implementation must be based on standards, not subjective judgments

ST. LOUIS, MISSOURI, USA, March 31, 2016 /EINPresswire.com/ -- The publisher of RxforAmericanHealth says that the Department of Human and Health Services (HHS) and National Institute of Health (NIH) must act to define standards for implementation of ‘march-in’ rights to help lower prescription medicine prices.
In an open letter to HHS Secretary Sylvia Burwell posted on RxforAmricanHealth, Daniel Hines says such action coupled with other initiatives including price negotiation for medicines, reciprocal Memorandums of Understanding between regulatory agencies of Tier One Countries as validation of the safety and efficacy of the oversight of personally imported medicines from those countries, criminal penalties for abuse of pricing practices based on a ‘what the traffic will bear’ philosophy, greater transparency in Pharma pricing practices, and an end to direct-to- consumer advertising for prescription medicines, will ensure a ‘stakeholder’ role for the American public that supports so much of Pharma R&D, by an increased presence of consumers, advocates and private citizens in policy development and hearings.
He notes that HHS Secretary Burwell recently denied a request from 50 members of Congress to implement march-in provisions leading to a number of Senators joining in support of the request aimed at cost increases of the Cancer drug Xtandi.
“While this issue has surfaced again as a request for similar action from even more Congressmen and advocacy groups regarding the Xtandi patent, it is the failure of HHS and NIH to face up to their responsibilities to take action in the public interest that is the greater concern,” Hines explains.
He says the “requests themselves are an exercise of the authority of Congress, as they are based upon long-standing (30 years) existing legislation that makes it evident that it is incumbent upon the agencies to take action when Congress believes it is appropriate.”
He cites a number of reasons in support of his contention:

- The function of the Health and Human Services is to ostensibly protect the health and well-being of Americans, while the National Institute of Health is the primary agency of the United States government responsible for biomedical and health-related research.
- A major responsibility of each is that is must address not only the safety and efficacy of medicines, but their availability as well since if a medicine is unavailable for any reason it creates a health care crisis for those patients who are derived of the potential benefit of the denied medicine;
- As the Congressional letter notes: ‘march-in rights’ should be asserted under 35 U.S.C. § (203)

(a)(2) “when action is necessary to alleviate health and safety needs are not being reasonably satisfied” or “benefits of a patented product are not available to the public on reasonable terms”;

- The current pricing crisis of vital medicines clearly not only do not ‘reasonably’ alleviate health and safety needs of Americans, but are actually contributing to endangering the health of patients who are denied the benefits of access to the benefits to be derived from a regimen of vital medicines;
- Likewise, this means that the “benefits” of a patented medicine are not available to the public since a product that is unaffordable is, in and of itself, unavailable and is “not available to the public on reasonable terms”;
- The linchpin for implementation of ‘march in’ action is the definition of ‘extraordinary circumstances’. Webster’s defines extraordinary as unusual or different from the usual. We can only hope that so many Americans being denied access to unaffordable medicines, the disastrous burden upon individual health, outrageous price increases over the past few years, and Direct-to-Consumer advertising of medicines that exceeds pharmaceutical industry research and development, are not considered to be usual, and that, instead, an ‘extraordinary’ situation does indeed exist.

“This places the responsibility upon HHS and NIH not to decide whether a circumstance is ‘extraordinary’ based upon personal whim and observation, devoid of any factual studies that represent standards,” Hines says.

“With that in mind, we urge steps be taken to clearly define standards that would constitute an ‘extraordinary’ situation, not only for higher-priced specialty medicines but for vital lower-priced maintenance prescriptions that have been priced beyond the reach of untold numbers of Americans leading to adverse health complications.”

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