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Press Release



For Immediate Release

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Governor Hassan Calls on FDA to Accelerate Consideration of Alternatives for Epinephrine Auto-Injectors

Governor Also Requests Recommendations for Legislative Action to Address Concerns Going Forward

CONCORD – In response to recent price increases of Mylan Pharmaceutical's epinephrine auto-injector, "EpiPen," Governor Maggie Hassan today sent a letter to the U.S. Food and Drug Administration (FDA), calling on the FDA to accelerate its consideration of competing products, including generic alternatives.

"Many Granite Staters have expressed their concerns about the impact of this price hike, especially as families are preparing to send their children back to school and needing to keep them safe from severe allergies," Governor Hassan wrote. "As those who care for children with severe allergies know all too well, an EpiPen can make the difference between life and death in an emergency. And carrying expired pens, as many families have been forced to do in light of these radically increased prices, puts those lives at risks."

According to recent reports, prices for EpiPen are as much as five times higher than they were in 2007. The FDA has considered generic alternatives to EpiPen, but it has yet to approve any of those versions.

"Given Mylan's recent price increases for EpiPen and the significant financial burden this is causing for families in New Hampshire and around the country, I believe working to ensure access to safe and affordable alternatives should be a top priority for your agency," Governor Hassan wrote. "I strongly encourage the FDA to accelerate its review and work to ensure that safe and affordable generic versions of EpiPen are able to come to market as quickly as possible."

In addition, the Governor requested that the FDA make recommendations for potential legislation to address concerns moving forward.

"I also ask that you provide recommendations for potential legislative remedies to help address similar concerns going forward and ensure that the FDA has the authority and resources it needs to help prevent similar situations from arising in the future," Governor Hassan wrote.

The full text of the Governor's letter to the FDA is below:

August 29, 2016

Commissioner Dr. Robert M. Califf
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I write to you today deeply concerned about Mylan Pharmaceuticals' recent alarming price increase for their epinephrine auto-injector, "EpiPen," and to respectfully request that the Food and Drug Administration accelerate its consideration of competing products, including new generic alternatives.

According to recent reports, Mylan has increased the price for the life-saving EpiPen device five-fold since they acquired the product in 2007. Many Granite Staters have expressed their concerns about the impact of this price hike, especially as families are preparing to send their children back to school and needing to keep them safe from severe allergies. As those who care for children with severe allergies know all too well, an EpiPen can make the difference between life and death in an emergency. And carrying expired pens, as many families have been

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forced to do in light of these radically increased prices, puts those lives at risks.

I understand that earlier this year the Food and Drug Administration (FDA) considered a generic alternative to EpiPen that could help alleviate some of the financial concerns caused by Mylan's price increases. However, the FDA has yet to approve this generic version.

Given Mylan's recent price increases for EpiPen and the significant financial burden this is causing for families in New Hampshire and around the country, I believe working to ensure access to safe and affordable alternatives should be a top priority for your agency. While I am encouraged that Mylan has announced its own generic version of the EpiPen, competing products can nonetheless help provide consumer choice and keep costs low for families. I support thorough reviews of new medications and encourage the FDA to conduct such reviews in this case. At the same time, I strongly encourage the FDA to accelerate its review and work to ensure that other safe and affordable generic versions of EpiPen are able to come to market as quickly as possible.

I also ask that you provide recommendations for potential legislative remedies to help address similar concerns going forward and ensure that the FDA has the authority and resources it needs to help prevent similar situations from arising in the future.

I thank you for your attention to this matter and eagerly await your response.

With every good wish,

Margaret Wood Hassan
Governor

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