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August 26, 2016

Dr. Robert M. Califf
Commissioner
U.S. Food and Drug Administration
1093 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf:

I write to express my concern over the recently reported substantial price increase of the Epinephrine Auto-Injector (EpiPen) manufactured by Mylan Pharmaceuticals, and to request that the Food and Drug Administration prioritize the introduction of safe and affordable generic alternatives. The affordability of epinephrine injectors is critical to the health of Americans at risk of anaphylaxis.

The EpiPen has been in use since 1977, yet, since acquiring the product in 2007, Mylan has steadily increased the price of EpiPen by over 400 percent. I recently met with constituents who expressed their consternation at the exponential price increase and worry they will not be able to access this life-saving treatment for their children. EpiPens expire after one year and, as more schools require students that suffer from severe allergies to carry EpiPens, families are forced to purchase costly replacements each school year. For families with high-deductible insurance plans, as well as those insured through Medicare, Medicaid, or the VA, or without insurance at all, the out of pocket costs for the EpiPen has become cost-prohibitive.

With the recall of competing product, Auvi-Q, in October 2015 and the recent rejection by the FDA of Teva Pharmaceutical's generic EpiPen alternative, Mylan is left to face virtually no market competition; leaving them space to aggressively promote their product while simultaneously increasing costs. Due to the price increase, families and first responders across America are reluctantly turning to cost saving alternatives. News outlets report the use of expired EpiPens and manual syringes, which require extensive medical training to ensure correct dosage and proper administration.

Following building public outrage, Mylan has already announced that they will increase the subsidy for those purchasing the EpiPen, which will be helpful to many who are struggling with the out of pocket cost. However, it does not resolve the underlying issue of a lack of a generic alternative, and the reality that some patients who need EpiPens will not have them due to their costs, putting them at risk of potentially fatal injury or lengthy and expensive medical treatment. For that reason, I ask that the FDA consider addressing any barriers that currently exist for emerging epinephrine treatments currently in development. Expediting the review process of alternative products will encourage healthy competition in the marketplace and ensure that this life-saving treatment will remain affordable for those that need it most. As the FDA continues its review process of potential new auto-injectable epinephrine devices, I

urge you to utilize all available resources and authorities to accelerate the process of approving safe and effective treatments to patients diagnosed with this, potentially fatal, condition.

To that end, I would ask that you respond in writing regarding the status of alternatives to the EpiPen currently under FDA review, and the timeline for approval, provided they prove safe and effective.

Thank you for your consideration. I look forward to your response and appreciate your attention to this important matter.

Sincerely,

Adam B. Schiff
Member of Congress