Congress of the United States
Washington, DC 20515

September 16, 2016

Robert M. Califf, M.D.
Commissioner
United States Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf,

We are writing to express our serious concerns regarding the near monopoly held by Mylan Pharmaceuticals on the EpiPen (epinephrine injection) Auto-Injector, which is used in emergency treatment for life-threatening allergic reactions. We have heard from many families who share our concern regarding the decreased access to this life-saving drug.

It is our understanding that the reason access to this drug has become an issue is due to its skyrocketing cost. The price for a two-pack has increased from an average of about $50 in 2004 to more than $300 each today. These price increases have created a significant cost burden on those who rely on them for anaphylactic emergencies. The continued price increase of EpiPens is a direct result of the absence of competition and an inefficient Food and Drug Administration (FDA) review process.

The shortage of competition has allowed Mylan to continue to increase prices for EpiPen, knowing that there is no generic version currently on the market. It is disappointing that the FDA recently rejected a request by a pharmaceutical company to start producing an alternative. This only makes affordable access more difficult for the 3.6 million Americans who rely on this device.

The FDA should seek to spur competition by streamlining the approval process in a way that reduces barriers to entry for pharmaceutical companies wishing to produce epinephrine auto injectors while ensuring all new products are safe for use. It would be helpful to know if the FDA could clarify whether any barriers exist to the approval of safe alternative products to EpiPen. We would also like to know how many alternatives to Mylan's EpiPen are currently being reviewed by the FDA and where they are in the review process.

Thank you in advance for your consideration. We would appreciate it if your office could supply us with a response by September 30, 2016. Should you have any questions or comments, please contact Taryn Dorfman, at 202.225.2015 or Taryn.Dorfman@mail.house.gov.

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Sincerely,

Steve Stivers
Member of Congress

Sean Duffy
Member of Congress

David P. Joyce
Member of Congress

Chris Stewart
Member of Congress

Bruce Poliquin
Member of Congress

Scott Garrett
Member of Congress

David Young
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