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August 22, 2016

VIA ELECTRONIC TRANSMISSION

Ms. Heather Bresch
Chief Executive Officer
Mylan
1000 Mylan Boulevard
Canonsburg, PA 15317

Dear. Ms. Bresch,

I am writing to request information regarding recent consumer concerns, including those expressed to me by Iowans, and media reports about the high cost of the Mylan EpiPen (epinephrine injection) Auto-Injector, which is used in emergency treatment for life-threatening allergic reactions. Access to epinephrine can mean the difference between life and death, especially for children. That is why the School Access to Emergency Epinephrine Act was signed into law in 2013^[1]. The law provides an incentive to states to boost the stockpile of epinephrine at schools. In addition, a number of states have passed laws requiring public schools to have epinephrine.

In 2007, Mylan purchased EpiPen from The Merck Group. Since the acquisition, the cost of EpiPen has risen over 400 percent^[2].

The substantial price increase has caused significant concern among patients. I have heard from one father in Iowa who recently purchased a refill of his daughter's EpiPen prescription. He reported that to fill the prescription, he had to pay over \$500 for one EpiPen. From other Iowans I have heard concerns about the cost of EpiPens and the need to replace them once a year when they expire. The high cost has also caused some first responders to consider making their own kits with epinephrine vials and syringes. For example, first responders in Seattle have developed such a kit and have sold them to public health agencies in five other states. Furthermore, there is a demonstration project in New York called "Check and Inject New York" which trains first responders to use syringe epinephrine kits in place of EpiPens to save money^[3].

In addition, schools are feeling the budgetary effects of needing EpiPens on hand in order to be prepared for emergency situations.

^[1] <https://www.congress.gov/bill/113th-congress/house-bill/2094/text>

^[2] <http://www.nbcnews.com/business/economy/epipen-price-hike-has-parents-kids-allergies-scrambling-ahead-school-n633071>

^[3] <http://theweek.com/articles/634878/america-dangerous-epipen-crisis>

The cost of an EpiPen prescription has implications for the federal taxpayers as well. Over 40% of children are insured through Medicaid or the Children's Health Insurance Program (CHIP). It follows that many of the children who are prescribed EpiPens are covered by Medicaid and therefore the taxpayers are picking up the tab for this medication.

In the case of EpiPens, I am concerned that the substantial price increase could limit access to a much-needed medication. In addition, it could create an unsafe situation for patients as people, untrained in medical procedures, are incentivized to make their own kits from raw materials.

In order to fully understand the pricing for EpiPens, please provide the following information:

1. What analyses were conducted by Mylan in determining the price of EpiPens?
2. What was Mylan's advertising budget for EpiPen in first half of 2016 as well as 2015?
3. Mylan has stated that the EpiPen has changed over time to better reflect important product features and the value the product provides^[4]. Please explain the changes Mylan has made to EpiPen since the acquisition that have caused it to increase the price and reflects the value the product provides.
4. Does Mylan provide a patient assistance program to help defray the cost of EpiPens to patients who need that help? If so, how much monetary assistance has been provided to patients in the past 5 years? Does Mylan have an arrangement with a non-profit organization in order to provide patient assistance for EpiPens? If so, what is the non-profit? And if so, how much monetary assistance has been provided to patients via the non-profit in the past 5 years?
5. What assistance programs exist to help school systems purchase EpiPens in order to be used, without a prescription, in an emergency situation? If such programs exist, how many school systems through the U.S. have used such a service in the past 5 years?

Thank you in advance for your cooperation with this request. Please number your responses according to their corresponding questions and respond no later than September 6, 2016. If you have questions, please contact my Health Policy Director, Karen Summar at Karen_summar@grassley.senate.gov or (202) 224-5225.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary

^[4] <http://theweek.com/articles/634878/america-dangerous-epipen-crisis>