United States Senate

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

WASHINGTON, DC 20510–6300

September 27, 2016

Mrs. Heather Bresch
Chief Executive Officer
Mylan, Inc.
Robert J. Coury Global Center
1000 Mylan Boulevard
Canonsburg, Pennsylvania 15317

Dear Mrs. Bresch:

I write to express my concern about the recent drastic price increase of the EpiPen Auto-Injector ("EpiPen") and to better understand some of the factors that may have contributed to Mylan's repeated price increases over the past several years. In particular, I am concerned about actions taken that may have delayed generic competition and would like to know more about how these practices relate to the significant price increases for EpiPens.

Americans – including many children – rely on the ready availability of epinephrine auto-injectors to provide rapid and potentially lifesaving treatment for anaphylactic allergic reactions. As the rate of serious food and other allergies continues to increase, epinephrine auto-injectors have become required items in more and more households, which is why in 2013 Congress overwhelmingly passed the *School Access to Emergency Epinephrine Act* to encourage schools to maintain a supply of epinephrine to treat students who experience severe allergic reactions.

While the EpiPen has saved thousands of lives, the steep price increases have compromised many families' access to this life-saving medication. In 2009, a set of two EpiPens cost $103.50 – today, the price has ballooned to over $600, forcing some first responders to use makeshift kits, and some families to use expired EpiPens or risk going without. The most recent increase in the price of the EpiPen is just the latest in a series of price hikes of nearly 500% over the past decade.

Mylan has repeatedly increased the price of the EpiPen in a market with virtually no comparable, competitive product. Although Teva developed and sought approval for its generic epinephrine auto-injector, that potential new product was the subject of patent litigation. In 2012, according to press releases, a settlement was reached that ended the lawsuit and required that Teva not launch a generic auto-injector until June 2015. While the details of the patent settlement with Teva remain confidential, publicly available information indicates that the agreement may resemble a "pay for delay" agreement, which have been criticized by regulators and antitrust experts as constraining competition and raising drug prices. The exact terms of the agreement, including under what circumstances any of the companies could bring a generic auto-injector to market, or if payments were made, are unknown.

Additionally, in January 2015, five months before the date Teva was permitted to launch a generic auto-injector under the agreement, Mylan filed a "Citizen Petition" with the Food and Drug Administration (FDA) requesting that the agency reject Teva's pending application. The petition was followed in April 2015 by a supplemental analysis submitted by Mylan concluding that patients could not use the generic Teva device correctly. The petitions were rejected by FDA.

As you are aware, in 2013, subsequent to the settlement agreement, the Supreme Court found in *Federal Trade Commission v. Actavis* that agreements between companies to delay the entry of a generic or competitor product into the marketplace can in some circumstances create a significant risk of unjustified anticompetitive effects in violation of federal antitrust laws. That type of agreement can result in one company retaining a virtual monopoly in a marketplace and control over the price of a drug.

In light of the Supreme Court's analysis, I am interested in understanding the structure of the settlement agreement with Teva, and how the fact that Mylan was aware a generic would likely enter the market at some point after 2015 impacted the company's decision to drastically increase both the retail and wholesale price of the EpiPen during that period.

To help me better understand how the price of the EpiPen skyrocketed so substantially over the past few years, and what role the agreement may have played, please provide the following information by October 7, 2016:

1. A copy of any and all agreements between Mylan, Meridian or its owners, and Teva regarding Teva's potential generic competitor, and all accompanying appendices, attachments or modifications to the agreement.
2. Any analysis in Mylan's possession, or funded or conducted by Mylan, that references Teva's generic epinephrine auto-injector.
3. A list of each EpiPen price increase undertaken by Mylan from 2009 to present that includes the date the decision was made to increase either the Wholesale Acquisition Cost (WAC) or the Average Net Price of the EpiPen and the date the price increase went into effect.
4. Any communications, including email communications, between April 2012 and present that references the current or future price of the EpiPen and also references Teva, including any mention of the status of filing, approval or any other regulatory development of Teva's application for a generic epinephrine auto-injector.

If you have any questions about this request, please contact Beth Stein on my Health, Education, Labor, and Pensions Committee staff at (202) 224-2931. I appreciate your attention and prompt response.

Sincerely,

Patty Murray

Patty Murray
United States Senator