United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

October 3, 2016

VIA ELECTRONIC TRANSMISSION

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

Dear. Ms. Bresch,

Thank you for your September 8, 2016 response to my letter. I also want to thank your team at Mylan for appearing at a briefing on September 14 for Judiciary Committee staff. I think it is important to maintain open lines of communication on this very important topic.

As I am sure your team has informed you, at the briefing Mylan was unable to answer some questions and pledged to respond at a later date. For purposes of clarity, I am listing the questions below.

I also want to bring to your attention recent news reports citing a statement of the Centers for Medicare and Medicaid Services (CMS) that said, "on multiple occasions, [CMS] provided guidance to the industry and Mylan on the proper classification of drugs and has expressly advised Mylan that their classification of EpiPen for purposes of the Medicaid Drug Rebate Program was incorrect."[1] During the Judiciary Committee staff briefing, a number of questions were asked about Mylan's justification for classifying the EpiPen as a non-innovator multiple source (NIMS) drug for purposes of the Medicaid Drug Rebate Program. In response to those questions, the personnel representing Mylan appeared to be unaware as to whether or not Mylan had ever received notice from CMS regarding the potential that its EpiPen was misclassified. Mylan personnel noted that they would follow up with an answer to that question.

Given CMS's recent statement that it "expressly advised Mylan that their classification of EpiPen for purposes of the Medicaid Drug Rebate program was incorrect" it is imperative that

[1] Diane Bartz, "U.S. Agency told Mylan that EpiPen was misclassified," Reuters (September 28, 2016). Available at http://www.reuters.com/article/us-congress-mylan-nl-idUSKCN11Y1X5

Mylan provide all documents relating to those communications so that the Committee can better understand Mylan's decision-making process with respect to classifying the EpiPen.

Accordingly, please answer the following questions and provide the requested documentation:

1. Was Mylan notified that the EpiPen was misclassified under the Medicaid Drug Rebate Program? If so, which government agency provided the notification, how was each notification made, and when was each made? Please provide all records relating to government communications to Mylan about the misclassification of the EpiPen.

2. If Mylan was notified about the misclassification, what steps did Mylan take to correct the misclassification? Please explain.

3. Please provide a copy of the Medicaid Rebate Agreement that Mylan signed to participate in the Medicaid Drug Rebate Program.

4. Please provide a clear accounting of the items reflected in the $608 product cost, including the amounts that go to wholesalers, retail pharmacies, pharmacy benefit managers, and payers, including the cost of goods sold. In addition, please provide the same cost structure breakdown for the authorized generic of the EpiPen.

5. Please provide the number of adverse events involving the old version of the product with the thumb prick design flaw.

6. Mylan's September 8 response said, "[o]ur understanding of this unmet need for this very important patient population drove our willingness to invest approximately $1 billion over the past eight years to increase awareness of anaphylaxis risk...." Please provide the following:

    a. All peer-reviewed articles that Mylan reviewed to determine this "unmet need."
    b. All statutory language that was used to define this "unmet need."
    c. All studies published by Mylan which describe this "unmet need."

7. Mylan's September 8 response said that "Mylan is working closely with insurance companies and others to explore EpiPen Auto-Injector's treatment as a preventive drug in order to further access for consumers." Please describe the basis for which Mylan believes the EpiPen Auto-Injector should be classified as a preventive drug.

Thank you in advance for your cooperation with this request. Please number your responses according to their corresponding questions and respond no later than October 18, 2016. If you have questions, contact Karen Summar at (202) 224-3744.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary