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October 3, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
200 Independence Ave, S.W.
Washington, D.C. 20201

Dear Mr. Slavitt:

I write today to request records relating to EpiPen's classification as a non-innovator multiple source (NIMS) drug for purposes of the Medicaid Drug Rebate Program. As you know, I wrote to you on August 30, 2016 regarding how much the Centers for Medicare and Medicaid Services (CMS) is paying for EpiPens given its price increases over the past several years. In addition to answering the questions in that letter, it would be helpful if CMS could provide more detail about its communications with Mylan regarding the NIMS classification.

Recent news articles have cited a statement from 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 Since it appears that CMS has determined Mylan's EpiPen is misclassified, knowing when and on how many occasions that notification was provided to Mylan is critical in determining how much money Mylan should have paid during the course of the rebate program. As you are aware, because Mylan has classified the EpiPen as a NIMS drug, it has been paying a 13 percent rebate under Medicaid. If it in fact is an innovator drug, Mylan should have been paying a rebate the greater of either 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the lower price available to any wholesaler, retailer, or provider.

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

Given the purported misclassification, the federal government and the states may have paid far more for EpiPens than required. It is imperative to understand what steps the Obama Administration has taken to remedy this overpayment. As you are aware, participants in the Medicaid Drug Rebate Program are required to sign a Rebate Agreement which provides the Secretary the authority to impose a civil monetary fine of \$100,000 for each item of false information filed by a participating company. In addition, this authority is also contained in §1927(b)(3)(C)(ii) of the Social Security Act. It would be helpful for Congress and the American public to understand what steps, if any, the Obama Administration has taken under its authorities to ensure companies are not gaming the system and are appropriately held accountable for misclassifying their products. Accordingly, please answer the following questions and provide the requested information:

1. All records relating to government communications with Mylan about the misclassification of the EpiPen.
2. For each notification from CMS that the EpiPen was misclassified under the Medicaid Drug Rebate Program, please detail how each notification was made, and when each was made.
3. Since Mylan was notified about the misclassification, what steps has it taken to correct the misclassification? Please explain.
4. What steps has the Obama Administration taken to ensure that the EpiPen was properly classified? Please explain.
5. Has the Obama Administration taken any steps to impose a civil monetary penalty, or any other penalties, upon Mylan for misclassifying the EpiPen? If so, please explain the steps. If not, why not?
6. Please describe the available legal authorities the Obama Administration can use to impose legal sanction, civil or otherwise, upon a company that knowingly fails to properly classify a drug under the Medicaid Drug Rebate Program.
7. Has CMS referred the EpiPen misclassification issue to the Office of Inspector General? If so, when? If not, why not?

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 Josh Flynn-Brown of my Judiciary Committee staff at (202) 224-5225.

Sincerely,



Charles E. Grassley
Chairman
Committee on the Judiciary