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

January 4, 2017

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,

Recently, my staff communicated with the office of the Health and Human Services Inspector General (HHS IG) regarding a report from July 2009 entitled "Accuracy of Drug Categorizations for Medicaid Rebates." As noted in the report, manufacturers must provide the Centers for Medicare & Medicaid Services (CMS) with the average manufacturer price (AMP) by national drug code (NDC) for each of their covered outpatient drugs.[1] The report detailed a number of drugs that the Inspector General studied to determine if drugs associated with NCDs were properly categorized in the AMP file. The report noted that eight of seventy-five NDCs that underwent a manual review appear to be "incorrectly categorized in the AMP file."[2] The report further noted that, "these NDCs should have been categorized by their manufacturers as innovators."[3]

According to emails acquired by the Committee from the Inspector General, on March 12, 2009, CMS staff requested the HHS IG provide a list of the misclassified drugs. On March 16, 2009, the HHS IG did so. In consultation with the HHS IG, my staff was informed that the misclassified drugs included EpiPen, Dilaudid, and Prilosec. I have previously written you asking what steps the Obama Administration took to hold Mylan accountable for misclassifying the EpiPen – you have failed to respond thus far. My request was in response to CMS declaring that "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." Given this public pronouncement, Congress and the American public have a right to know what additional steps, if

[1] Health and Human Services Inspector General, "Accuracy of Drug Categorizations for Medicaid Rebates," at i (July 2009).
[2] *Id.* at 19.
[3] *Id.* at ii.

any, CMS took to hold Mylan and other companies accountable and CMS has an obligation to answer.

These misclassifications could have cost the taxpayers and states hundreds of millions of dollars. The Obama Administration's silence on these issues is unwarranted and irresponsible. Accordingly, in addition to my previous requests regarding EpiPen, please respond to the following:

1. Please provide all records relating to government communications with Purdue Pharmaceuticals and AstraZeneca regarding the misclassification of Dilaudid and Prilosec.

2. What steps has CMS taken to ensure that these drugs were properly classified?

3. Has CMS notified Purdue and AstraZeneca that its drugs were misclassified? If so, how was each notification communicated, when was each communication made, and what did each company do in response?

4. Has CMS determined how much the taxpayers and states have overpaid for these drugs? If so, how much? If not, why not?

5. Has the Obama Administration taken any steps to impose a civil monetary penalty, or any other penalties, upon Purdue or AstraZeneca for misclassifying their drugs? If so, please explain the steps. If not, why not?

Please number your responses according to their corresponding questions and respond no later than January 18, 2017. 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