DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

MAY 31 2017

Josh Flynn-Brown
Investigative Counsel
United States Senate
Committee on the Judiciary
Washington, DC 20510

Dear Mr. Flynn-Brown:

We previously discussed with you the Office of Inspector General's (OIG) work related to the Medicaid Drug Rebate Program and EpiPen, a product marketed and sold by Mylan Specialty L.P. (Mylan). Specifically, these discussions centered on the appropriate classification of EpiPen for purposes of the Medicaid Drug Rebate Program.

Based on those conversations, you made two requests of OIG for additional analysis. First, you asked whether we could expand calculations made in published OIG work to determine the dollar amount of additional rebates that Mylan may have owed if EpiPen had been classified as an innovator (i.e., brand-name) product rather than as a non-innovator (i.e., generic) product under the Medicaid Drug Rebate Program.

In response to your request, on February 10, 2017, we provided you with an estimate of the difference between the rebate amounts that Mylan owed for EpiPen as a generic and may have owed had it classified EpiPen as a brand-name drug (Estimated Rebate Differential). We generated the Estimated Rebate Differential for 2006 through 2014 using the data, timeframe, and methodological assumptions from our prior work.

Second, you asked OIG to determine the Estimated Rebate Differential for 2015 and 2016. In response, we used additional data and generated an Estimated Rebate Differential for the entire period under discussion (2006 through 2016).

Please note that our analysis has several important limitations. First, the absence of Best Price information limited OIG's calculation of the basic rebate amount to a percentage of average manufacturer price (AMP). Second, we did not analyze several issues outside of the Estimated Rebate Differential necessary to understanding the broader context of Medicaid expenditures for EpiPen. OIG did not perform an analysis of State supplemental rebates that are likely to impact Medicaid's overall expenditure for EpiPen. Nor did we determine whether Mylan's classification of EpiPen under the Medicaid Drug Rebate Program was actually correct or the amount, if any, of rebates that the Federal Government should seek to recover from Mylan.

The classification of a drug is a key factor in determining the amount of rebates that a manufacturer owes under the Medicaid Drug Rebate Program. Generally, manufacturers owe higher rebate amounts for brand-name drugs than for generic drugs. The basic rebate amount for a generic drug is based on a percentage (currently 13 percent) of its AMP. The formula for calculating the rebate amount for a brand-name drug is more complex. The basic rebate amount for a brand-name drug is based on the greater of two figures: a fixed percentage (currently 23.1 percent) of the drug's AMP or the difference between the drug's AMP and Best Price. Whichever formula yields the higher value determines the brand-name drug's basic rebate amount. Manufacturers report AMPs and, for brand-name drugs, Best Prices to the Centers for Medicare & Medicaid Services (CMS).

Manufacturers of brand-name products are required to pay an inflation-related rebate amount, in addition to the basic rebate amount, if a drug's price has increased faster than the rate of inflation. Beginning in 2017, manufacturers of generic products have also been required to pay inflation-related rebate amounts.

As we discussed, Mylan has historically classified EpiPen as a generic for purposes of the Medicaid Drug Rebate Program. Therefore, the rebates that Mylan paid for EpiPen were based on a percentage of AMP. In contrast, if Mylan had classified EpiPen as a brand-name product, it should have calculated rebates based on the greater of a higher percentage of AMP or the difference between AMP and Best Price. In addition, if EpiPen had been classified as a brand-name product, Mylan would have been required to pay inflation-related rebate amounts for EpiPen if its price increased faster than the rate of inflation. Based on the methodology and limitations described below, we determined the Estimated Rebate Differential to be $1.27 billion for 2006 through 2016.

This letter provides the Estimated Rebate Differential covering the entire timeframe under discussion (2006 to 2016) to ensure consistency in methodological approach between the two requested estimates.

OIG obtained AMP and utilization data from CMS's Medicaid Drug Rebate (MDR) system, and we obtained consumer price index data from the Bureau of Labor Statistics. We used AMP data to calculate the basic rebate component of the Estimated Rebate Differential. We used consumer price index data and AMP data to determine the inflation-related rebate component of the Estimated Rebate Differential. OIG followed statutory guidance for calculating the inflation-related rebate amount. Please note that OIG's analysis has several important limitations. As previously noted, calculating a brand-name drug's basic rebate amount requires applying two formulas to the drug pricing data and then selecting whichever method yields the higher value. Mylan did not report Best Price information to CMS for EpiPen. Because Best Price was not available, we could perform only one of the two calculations required for determining the basic rebate amount. Therefore, we estimated the basic rebate amount using only the percentage of AMP formula. OIG did not verify the accuracy of the AMP data reported in CMS's MDR system for EpiPen products.

Finally, it is important to consider the Estimated Rebate Differential in a broader context. For purposes of this letter, OIG's analysis was limited in scope. We did not perform an analysis of other factors, such as State supplemental rebates, that are likely to impact Medicaid's overall expenditure for EpiPen. OIG has no information about any State supplemental rebate arrangements for EpiPen.

Furthermore, OIG did not determine whether Mylan's classification of EpiPen under the Medicaid Drug Rebate Program was actually correct nor did we determine the amount of rebates, if any, the Federal Government should seek to recover from Mylan now. We did not consider any facts that might be relevant to such determinations.

If you have questions, please contact me or Anne Rohall-Andrade, Attorney Advisor, Congressional Affairs, at [redacted]

Sincerely,

Christopher S. Seagle
Director of External Affairs