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

November 8, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Daniel R. Levinson
Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue SW
Washington, DC 20201

Dear Inspector General Levinson,

Recently, my staff communicated with yours regarding an Inspector General 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 then details a number of drugs that your office studied to determine if drugs associated with NDCs were properly categorized in the AMP file. The report noted that eight of seventy-five NDC's that underwent a manual review by your staff appear to be "incorrectly categorized in the AMP file."[2] The report further noted that, "these NDCs should have been categorized by their manufactures as innovators."[3]

With respect to those eight, your staff has stated that the EpiPen was one of those drugs and that your office reported the misclassification to CMS in 2009. My staff requested a briefing as well as records pertaining to the notice of misclassification to CMS and were informed it would require a formal letter from the Chairman.

Accordingly, please provide all records relating to the Health and Human Services Inspector General notifying CMS of the EpiPen's misclassification. If you have questions, please contact Josh Flynn-Brown of my Judiciary Committee staff at (202) 224-5225.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary

[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.