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

September 6, 2016

VIA ELECTRONIC TRANSMISSION

Mr. Tom Miller
Attorney General of Iowa
Hoover State Office Building
1305 E. Walnut Street
Des Moines, Iowa 50319

Dear Attorney General Miller:

I have written several letters regarding concerns about the high price of Mylan's EpiPen to include a letter to Mylan, the Food and Drug Administration, and the Centers for Medicare and Medicaid Services. In each letter I have voiced concern that the substantial price increase, from about $57 in 2007 to approximately $600 or more today, could limit access to much-needed medication for Iowans. I have heard from hundreds of Iowans, to include many mothers and fathers, who are struggling to pay for EpiPens for their children who suffer from severe allergic reactions. Further, I have noted that the substantial price increase will have an impact on school budgets when schools keep the drug on hand for emergencies and impact state and federal health care programs funded by taxpayers, such as Medicaid and the Children's Health Insurance Program (CHIP). Just last week, the Minnesota Attorney General opened an inquiry into Mylan's pricing of the EpiPen and its effect on the people of Minnesota, including its school system. Today, I write to you to request that you follow the Minnesota Attorney General's initiative and review the issue of whether the people of Iowa have been overcharged for EpiPens. I will also be looking into this matter.

Recently, some of my colleagues in the Senate have noted that Mylan's EpiPen may have been misclassified as a generic drug which, according to the Minnesota Department of Health and Human Services, may have cost the state more than $4 million in overpayments in a single year. In my letter to the Centers for Medicare and Medicaid Services I asked about this potential misclassification.[1] As you are aware, under the current laws, companies offering branded drugs and authorized generic drugs must provide a rebate to the federal government that consists of the

[1] My colleagues, Senators Klobuchar and Blumenthal, joined me on that letter.

greater of either 23.1 percent of the Average Manufacturer Price (AMP) or the AMP minus the lowest price available to any wholesaler, retailer, or provider. However, non-innovator multiple source drugs, also called generic drugs, are subject to a lower rebate requirement of 13 percent. Apparently, Mylan's EpiPen may have been misclassified as a non-innovator multiple source drug for purposes of the Medicaid Drug Rebate Program, which only requires the 13 percent rebate rather than the 23.1 percent rebate. Thus, if this classification is in fact incorrect, Mylan has been only paying the 13 percent rebate and as a result, the state of Iowa, just like Minnesota, may have paid more for the EpiPen than it should have.

If Minnesota has been potentially overcharged to the tune of $4 million, so too could Iowa. And if that is the case, the people of Iowa ought to be reimbursed for the overcharge. It goes without question that the people of Iowa work very hard for their money, which is why I have committed to intense oversight of not just the federal government and its spending habits, but oversight of private companies that profit handsomely off federal and state government programs supported by Iowans' taxpayer dollars.

The cost of EpiPens hits home for all of us. We all know someone who has a severe, life-threatening allergy that may require the use of emergency medicine like an EpiPen. Iowans are rightly concerned about the high price of EpiPens. Accordingly, I urge you to review whether the state of Iowa and the people of Iowa have been overcharged by the potential misclassification of Mylan's EpiPen as a generic drug. Please advise on what steps you are taking, or intend to take, on whether Iowa was overcharged, and if so, by how much. In addition, it would also be helpful to know how much Iowa has spent on EpiPens in the past five years. This information will be helpful as Congress works to understand whether the generic drug classification system is working as intended and whether drug companies and the Centers for Medicare and Medicaid Services are fulfilling their responsibilities under the program. I would appreciate a response by September 20, 2016.

Sincerely,

Chuck Grassley

Charles E. Grassley
Chairman
Committee on the Judiciary