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October 11, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Loretta E. Lynch
Attorney General
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530

Dear Attorney General Lynch,

This past Friday news reports indicated that the Justice Department and Mylan entered into a settlement for \$465 million for misclassifying its EpiPens as a non-innovator multiple source drug (NIMS) for purposes of the Medicaid Drug Rebate Program.¹ That same evening, Mylan released a statement confirming the settlement and noted the terms “do not provide for any finding of wrongdoing [...]”² I have written several letters on the misclassification issue, including two addressed to Mylan and one previous letter to the Justice Department.³ To date, the Department has yet to respond.

In addition, I have written two letters to the Centers for Medicare and Medicaid Services (CMS), the most recent of which asks CMS when it first notified Mylan that the EpiPen was misclassified as a NIMS drug. In that letter, I cited news reports that quoted CMS saying that it “expressly advised Mylan that their classification of EpiPen for purposes of the Medicaid Drug Rebate Program was incorrect.”⁴ It is critical to understand when CMS first notified Mylan of the misclassification to determine the potential time period for which it failed to pay the 23.1 percent rebate under the Medicaid drug program and instead paid the 13 percent rebate. Determining how many years Mylan was out of compliance will provide a better understanding

¹ Ben Popken, “Mylan Agrees to Settle with DOJ for \$465 Million Over EpiPens,” NBC News (October 7, 2016). Available at <http://www.nbcnews.com/business/consumer/mylan-settles-doj-465-million-over-epipens-n662196>

² Mylan Press Release, October 7, 2016. Available at <http://newsroom.mylan.com/2016-10-07-Mylan-Agrees-to-Settlement-on-Medicaid-Rebate-Classification-for-EpiPen-Auto-Injector>

³ The letter to the Justice Department, dated September 28, 2016, was with Senators Klobuchar and Blumenthal.

⁴ 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>.

as to whether or not the \$465 million settlement adequately covers the years in which Mylan knew its product was misclassified.

Further, it is critical to know when the Justice Department began an investigation into Mylan and the precise terms of the settlement agreement. If the Obama Administration has been on notice for a number of years about the EpiPen misclassification, it begs the question why the Administration waited so long to enforce the law all the while letting the taxpayers and states pay millions of dollars more for EpiPens than they should have. News reports indicate that Mylan will not reclassify the EpiPen until April of next year.⁵ Given that CMS has said Mylan misclassified its EpiPen, why is Mylan not required to reclassify the EpiPen *immediately*? An immediate reclassification would help prevent Mylan from further over-charging the states under the Medicaid Drug Rebate Program.

It is particularly important to know what the \$465 million covers and where that money will go. Given that Mylan has apparently overcharged Medicaid, presumably a portion of the \$465 million will be returned to the states to make them whole. However, details have been lacking and even though Mylan has publicly announced the settlement, the Justice Department is thin on details saying, “[t]he Justice Department does not confirm or deny the existence of an investigation.”⁶ Now, more than ever, the Justice Department should be open and transparent with the American people. It is the taxpayers and the states that Mylan’s misclassification victimized. Many Iowans have talked to me or written letters about their struggles to afford the EpiPen. And recent news reports indicate that Mylan may have failed to pay over \$700 million to Medicaid over the past five years, much more than the current settlement.⁷ The people and the states need to be assured that the \$465 million settlement will make them whole.

Accordingly, please answer the following:

1. Will the settlement require Mylan to immediately reclassify the EpiPen under Medicaid? If so, what will EpiPen’s new classification be? If not, why not and when will Mylan be required to reclassify the EpiPen?
2. Will the settlement require Mylan to reimburse the states for paying the 13 percent rebate instead of the 23.1 percent rebate? If so, please detail how much money will go to each state and how many years the payment to each state will cover for the misclassification. If not, why not?
3. Please provide a detailed breakdown of the \$465 million to show each federal government or state account that will receive a portion of the settlement.

⁵ Katie Thomas, “Mylan to Settle EpiPen Overpricing Case for \$465 Million,” The New York Times (October 7, 2016). Available at http://www.nytimes.com/2016/10/08/business/epipen-mylan-justice-department-settlement.html?_r=0

⁶ Ben Popken, “Mylan Agrees to Settle with DOJ for \$465 Million Over EpiPens,” NBC News (October 7, 2016). Available at <http://www.nbcnews.com/business/consumer/mylan-settles-doj-465-million-over-epipens-n662196>

⁷ Christina Cheddar Berk, “Mylan in \$465 million settlement over EpiPen classification; trims forecast,” CNBC (October 7, 2016). Available at <http://www.cnbc.com/2016/10/07/mylan-agrees-to-465-million-settlement-with-government-over-epipen-classification.html>

4. When did the Justice Department begin its investigation into Mylan?
5. When did the Justice Department begin settlement negotiations with Mylan?
6. Which Justice Department components were involved in the investigation?
7. Are there any other government agencies besides the Justice Department that are a party to the settlement? If so, please name each agency.
8. Did the Justice Department find that CMS was accurate in saying that the EpiPen was misclassified for purposes of the Medicaid Drug Rebate Program?
9. Did the Justice Department determine how many years the EpiPen was misclassified? If so, how many? If not, why not?
10. Please explain why the Justice Department believes \$465 million is a reasonable and proportionate settlement in light of the purported wrongdoing and potential damages suffered by taxpayers, to include potential actions under the False Claims Act which could result in treble damages paid to the taxpayers.
11. In light of the fact the Justice Department has released settlements to the public before,⁸ and in light of the fact Mylan has already publicly commented on the terms of the settlement, will the Department publish the settlement in full with Mylan? 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 25, 2016. 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

⁸ There are many examples, but for one example please see Press Release, "Bank of America to Pay \$16.65 Billion in Historic Justice Department Settlement for Financial Fraud Leading up to and During the Financial Crisis," (August 21, 2014) and settlement terms linked at <https://www.justice.gov/opa/pr/bank-america-pay-1665-billion-historic-justice-department-settlement-financial-fraud-leading>