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November 1, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Ashton Carter
Secretary of Defense
Department of Defense
1000 Defense Pentagon
Washington, DC 20301

Dear Secretary Carter:

I am writing today regarding the Department of Defense's (DoD) spending on the EpiPen purchases in light of the recent news reports about the EpiPen's substantial price increases. The EpiPen is used in emergency treatment for life-threatening allergic reactions. The auto-injection pen device, that is the basis for the EpiPen, was originally developed in the 1970s for the military to protect soldiers in the event of chemical warfare.¹ Today, Pfizer's subsidiary, Meridian Medical Technologies, owns the patent for the actual injection pen and has licensed it to Mylan.² Mylan has raised the price for the EpiPen by more than 500 percent, from \$57 when it acquired the product in 2007 to more than \$600 in 2016.³ Although the cost of the main ingredient in an EpiPen is extremely inexpensive—epinephrine costs about a dollar—prices for the device have skyrocketed.

According to information obtained by the Committee, in fiscal year 2016, DoD spending on EpiPens rose to over \$57 million over the past year from \$9 million in 2008—an increase mostly driven by price hikes. Given the importance of this topic, it is imperative to understand the costs associated with DoD's purchases of the EpiPen. Through TRICARE, DoD offers prescription drug benefits to over 9 million active duty service members, their dependents and

¹ Matt Reimann, "The Story of the EpiPen: from Military Technology to Drug-Industry Cash Cow," Timeline (August 24, 2016). Available at <https://timeline.com/epipen-technology-drug-industry-b28d19036dee#.72mbsi2f2>

² David Martin, "The Real EpiPen Scandal We Should be Talking About," CNBC (August 25, 2016). Available at <http://www.cnbc.com/2016/08/25/the-fda-and-congress-share-the-blame-for-outrageous-epipen-prices-commentary.html>

³ Aaron E. Carroll, "The EpiPen, a Case Study in Health Care System Dysfunction," The New York Times (August 23, 2016). Available at <http://www.nytimes.com/2016/08/24/upshot/the-epipen-a-case-study-in-health-care-system-dysfunction.html?smid=tw-upshotnyt&smtyp=cur&r=0>

retirees of the uniformed services.⁴ Beneficiaries may fill prescriptions at military treatment facilities (MTF), through a mail order pharmacy, or at retail pharmacies participating in the TRICARE Retail Pharmacy Network (“TRRx”).⁵ Pursuant to the Veterans Health Care Act of 1992, DoD is entitled to federal prices for EpiPen purchases for its beneficiaries in military treatment facilities and the TRICARE Mail Order Pharmacy (TMOP); and through authority provided in the 2008 NDAA is entitled to receive the same discounts in the retail pharmacy network.⁶ In 2012, the VA signed a five year contract with Mylan setting the federal supply schedule (FSS) price for EpiPen at \$183 per pack.⁷ Yet, the DoD paid significantly more to access the EpiPen at retail network pharmacies.

DoD paid the lowest prices for MTF and TMOP prescriptions—ranging from \$97 to \$169, and \$87 to \$173 respectively in fiscal years 2008 through 2016. However, DoD’s retail network price for EpiPens has gone up 80 percent since 2008. In fiscal year 2008 DoD paid \$94 (slightly lower than the MTF and TMOP prices) for the EpiPen, but the price reached \$509 in fiscal year 2016. It is important to understand why DoD retail network pharmacies are paying 60 percent more for the same product, when it appears DoD is entitled to receive significant discounts in the retail pharmacy network.

While I recognize that the prescription drug market is very complex and various factors impact prices, DoD generally pays lower drug prices due to discounts mandated by law and negotiated rebates. DoD needs to enforce this authority and ensure that the government and civilians receive maximum discounts on high-cost prescriptions, such as the EpiPen.

To better understand these issues, please answer the following:

1. Over the past 10 years, what price did the DoD negotiate for MTF, TMOP, and retail network pharmacy EpiPen purchases? Please describe the process for negotiating these prices.
2. Please describe the process by which drugs such as the EpiPen are classified by the DoD.
3. With respect to the current classification of the EpiPen as a non-innovator multiple source drug, and given the fact it has been misclassified as such, how much money has the DoD lost in rebates due to that misclassification? Does the DoD have the ability to recover the rebates? If so, please explain.

⁴ Covington and Burling LLP, Legal Summary on Section 703 of the National Defense Authorization Act. Available at <https://www.cov.com/~/media/files/corporate/publications/2009/03/dod-final-rule-mandates-deeply-discounted-pricing-for-tricare-retail-pharmac.pdf>

⁵ *Id.*

⁶ Through authority provided in Section 703 of the 2008 National Defense Authorization Act (NDAA) and the final rule implementing the regulation requires that all TRRx prescriptions be treated as if they were purchased by DoD and thus priced at or below the federal ceiling price.

⁷ Veteran Affairs, National Acquisition Center, Pharmaceutical Catalog Search, Available at <http://www.va.gov/nac/Pharma/Details?NDC=49502050102&CNT=V797P-2070D> (last visited October 13, 2016).

4. Please explain why DoD does not receive the same discounts applied to MTF and TMOP purchases or federal supply schedule prices for EpiPens purchased from retail network pharmacies.
5. Does DoD purchase EpiPens exclusively from Mylan? If not, please list the other epinephrine auto-injectors it has purchased, the volume of purchase, and the cost.
6. How many alternatives to Mylan's EpiPen are currently being reviewed by DoD? If available, please provide a list of the alternative companies and prices that are being considered.

Thank you in advance for your cooperation with this request. Please number your responses according to their corresponding questions and respond no later than November 15, 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