

CHARLES E. GRASSLEY, IOWA, CHAIRMAN

ORRIN G. HATCH, UTAH
JEFF SESSIONS, ALABAMA
LINDSEY O. GRAHAM, SOUTH CAROLINA
JOHN CORNYN, TEXAS
MICHAEL S. LEE, UTAH
TED CRUZ, TEXAS
JEFF FLAKE, ARIZONA
DAVID VITTER, LOUISIANA
DAVID A. PERDUE, GEORGIA
THOM TILLIS, NORTH CAROLINA

PATRICK J. LEAHY, VERMONT
DIANNE FEINSTEIN, CALIFORNIA
CHARLES E. SCHUMER, NEW YORK
RICHARD J. DURBIN, ILLINOIS
SHELDON WHITEHOUSE, RHODE ISLAND
AMY KLOBUCHAR, MINNESOTA
AL FRANKEN, MINNESOTA
CHRISTOPHER A. COONS, DELAWARE
RICHARD BLUMENTHAL, CONNECTICUT

United States Senate

COMMITTEE ON THE JUDICIARY

WASHINGTON, DC 20510-6275

KOLAN L. DAVIS, *Chief Counsel and Staff Director*
KRISTINE J. LUCIUS, *Democratic Chief Counsel and Staff Director*

November 1, 2016

VIA ELECTRONIC TRANSMISSION

The Honorable Robert A. McDonald
Secretary
U.S. Department of Veterans Affairs
810 Vermont Avenue NW
Washington, DC 20420

Dear Secretary McDonald:

I am writing today regarding the Department of Veterans Affairs (VA) spending on the Mylan EpiPen 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.

Given the importance of this topic, it is imperative to understand the VA's role with respect to negotiating EpiPen purchase prices for the "Big Four" and the costs associated with federal government purchases of the EpiPen. Under the Veterans Health Care Act of 1992⁴, the VA has the authority to negotiate prices for brand-name drugs purchased by the four largest federal purchasers—VA, Department of Defense (DoD), Public Health Service (including the

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>

⁴ *Veterans Health Care Act of 1992*, Public Law No. 102-585, 106 Stat. 4971, §603(a)(1), (November 2, 1992).

Indian Health Service), and the U.S. Coast Guard.⁵ Since 2009, the VA has granted Mylan contracts valued at nearly \$3 billion⁶, including at least \$6 million for pharmaceutical drug purchases.⁷ In 2012, the VA signed a five year contract with Mylan to purchase the EpiPen for \$183 per pack.⁸ It is not clear how much the VA has spent on EpiPens overall.

Given the VA's responsibility in the negotiation on behalf of its own purchases as well as its role with respect to the negotiations on behalf of the Big Four, it is important for Congress and the public to better understand the significant role the agency plays and the effect it has on drug spending. According to a recent report, DoD's supplier, Meridian Medical Technologies, sells similar auto-injectors exclusively to DoD, Emergency Medical Services, and over 30 nations around the world for use by U.S. military personnel and emergency medical personnel for urgent care situations⁹ for under \$50 a unit.¹⁰ The U.S. military primarily uses Meridian's AtroPen auto-injector to deliver Atropine first aid when military personnel are exposed to chemical warfare agents. Despite the difference in the administered drug, Meridian's device is very similar. Yet, the VA is paying more than 70 percent more to access the EpiPen. It is important to understand why the government is paying a vastly different price for such similar products from the same manufacturer.

While I recognize that the prescription drug market is very complex and various factors impact prices, considering the common purpose of DoD and VA's use of auto-injector devices, it seems as if the VA may be able to obtain additional savings on the EpiPen. To better understand these issues, please answer the following:

1. Please describe the process for negotiating the federal supply schedule and Big Four prices with Mylan for EpiPen purchases.
2. Please describe the process by which drugs such as the EpiPen are classified by the VA.
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

⁵ Big Four prices for pharmaceutical products based on statutorily-required pricing calculations and are only available to VA, Department of Defense (DoD), Public Health Service, and U.S. Coast Guard. The price to the Big Four for a brand-name drug is the lower of the Federal Supply Schedule price or the cap.

⁶Patricia Sabatini and Len Boselovic, "Mylan acquires foreign drug business", Pittsburgh Post-Gazette (July 15, 2014). Available at <http://www.post-gazette.com/business/2014/07/14/Mylan-to-buy-Abbott-business-line-in-5-3-billion-deal/stories/201407140129>

⁷USASpending.Gov, Advanced Data Search, <https://www.usaspending.gov/Pages/AdvancedSearch.aspx?sub=y&ST=C,G,L,O&FY=2017,2016,2015,2014,2013,2012,2011,2010,2009,2008&A=0&SS=USA&RN=mylan&pidx=1&SB=RN&SD=ASC> (last visited October 13, 2016).

⁸ 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).

⁹ http://www.medicalproductguide.com/companies/5907/meridian_medical_technologies_inc

¹⁰ 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>

much money has the VA lost in rebates due to that misclassification? Does the VA have the ability to recover the rebates? If so, please explain.

4. With respect to Big Four purchases of EpiPen and AtroPen over the past 10 years, what price did the VA negotiate?
5. How much has the VA actually paid for EpiPens over the past 10 years? Please list by each year.
6. In the past 10 years, how many EpiPens has the VA purchased? Please list by each year.
7. Does the VA purchase EpiPens exclusively from Mylan? If not, please list the other epinephrine auto-injectors it has purchased, the volume of purchase, and the cost.
8. How many alternatives to Mylan's EpiPen are currently being reviewed the VA? 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