

United States Senate

WASHINGTON, DC 20510

September 6, 2016

Andrew M. Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W
Washington, DC 20201

Dear Mr. Slavitt:

We are writing with regards to the impact of price increases and other recent initiatives for Mylan's EpiPen on programs administered by the Centers for Medicare and Medicaid Services (CMS).

As you are likely aware, the EpiPen made up over 87% of U.S. epinephrine auto-injector prescriptions in 2015.¹ The price of a two-pack of EpiPens has increased by over 400% since Mylan Pharmaceuticals acquired the product in 2007, with prices now more than \$730 for a set of two EpiPens, a well-documented and exorbitant increase.² Even though there are some epinephrine delivery devices on the market, none are as well-known or relied upon as Mylan's EpiPen. While Mylan has taken small steps in recent weeks to respond to widespread criticism, we remain concerned about the drug's impact on government spending for Medicaid, Medicare, and the Children's Health Insurance Program (CHIP).

As you may know, Mylan has responded to public scrutiny of EpiPen's price increase by offering pharmacy coupons and expanding eligibility for its patient assistance program for uninsured and under-insured patients. Additionally, Mylan has announced the introduction of an authorized generic product identical to the branded EpiPen. However, Mylan has not actually lowered prices for EpiPen, and programs administered by CMS are not eligible for these coupons. As a result, these incremental steps may cut the price of EpiPen for some privately insured individuals, but government health care programs, and ultimately the American taxpayer, will still be on the hook for the full price of the product.

Federal spending on prescription drugs has increased dramatically in recent years and American taxpayers are footing the bill. For example, from 2013 to 2014, spending on Medicare

¹ Cillizza, Chris. "The Price of EpiPens Has Gone up 450 Percent since 2004. That's Ridiculous." Washington Post. August 22, 2016. Accessed August 31, 2016. <https://www.washingtonpost.com/news/the-fix/wp/2016/08/05/the-price-of-epipens-has-gone-up-450-percent-since-2004-thats-unbelievable/>.

² Cohn, Meredith. "EpiPens Needed by Those with Severe Food Allergies Are Getting Expensive." Baltimoresun.com. August 19, 2016. Accessed August 31, 2016. <http://www.baltimoresun.com/health/blog/bal-cost-of-epipens-story.html>.

Part D grew 17 % according to CMS data.³ In this context, we believe it is important to gain a better understanding of the impact that Mylan's EpiPen price increases and the company's announced launch of an authorized generic will have on federal health programs. Therefore, we respectfully request your response to the following questions:

1. Under Medicaid, Medicare, CHIP and other federal and state healthcare programs, the government is most likely a significant purchaser of the EpiPen and EpiPen Jr.
 - a. What are the total costs to Medicare, Medicaid, and CHIP for EpiPen and EpiPen Jr., and how have these costs changed as prices have increased?
 - b. What is the breakdown of costs associated for each program for EpiPen and EpiPen Jr.?
2. What impact, if any, will Mylan's creation of the savings card and the expansion of patient assistance programs have on program spending for the EpiPen and EpiPen Jr. in Medicare, Medicaid, and CHIP?
3. Pharmaceutical companies commonly offer similar savings cards and patient assistance programs to consumers. What impact, if any, do these offerings have on program spending in Medicare, Medicaid, and CHIP?
4. On August 29, 2016, Mylan announced the introduction of an authorized generic product identical to the EpiPen but priced at \$300. This price is less than the branded EpiPen but still significantly more expensive than its price in 2007. What impact, if any, will the introduction of the authorized generic have on program costs to Medicare, Medicaid, and CHIP?
5. What impact, if any, will the introduction of the authorized generic EpiPen have on costs to beneficiaries enrolled in Medicare, Medicaid, and CHIP?
6. What barriers, such as, patient preference, consumer incentives and co-payments, physician knowledge or habit, and existing plan formularies and contracts, will limit CMS program uptake of the authorized generic, and what impact do you anticipate these limitations will have on changes to program spending?
7. In general, what is the impact of such authorized generics drugs on CMS program spending in Medicare, Medicaid, and CHIP?

Sincerely,



Benjamin L. Cardin
United States Senator



Mark. R. Warner
United States Senator

³ McIntire, Mary Ellen. "Medicare Part D Drug Spending Grew 17 Percent in 2014, CMS Data Shows - Morning Consult." Morning Consult. August 18, 2016. Accessed September 01, 2016. <https://morningconsult.com/alert/medicare-part-d-drug-spending-grew-17-percent-2014-cms-data-shows/>.



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