

United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510-6250

September 4, 2018

CHRISTOPHER R. HIXON, STAFF DIRECTOR
MARGARET E. DAUM, MINORITY STAFF DIRECTOR

The Honorable Alex M. Azar II
Secretary
U.S. Department of Health and Human Services
200 Independence Ave. SW
Washington, DC 20201

Dear Mr. Secretary:

At a hearing of the Senate Committee on Finance in April 2018, I asked Admiral Brett P. Giroir, the Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS), whether HHS had demanded explanations from pharmaceutical manufacturers that had raised prices for the opioid overdose reversal drug naloxone.¹ Admiral Giroir stated he had not asked the companies to explain their dramatic price increases, but promised he would “get back to [me] on whether [he] could write a letter.”² I am not aware, however, of outreach from HHS to my office on this issue.³

As you know, the price of two doses of the Evzio naloxone product, manufactured by Kaléo Pharma, increased from \$690 in 2014 to \$4,500 in 2016—more than 500%.⁴ Similarly, Hospira, Inc., increased the price for a certain naloxone injectable product by 129% between 2012 and 2016, and Amphastar Pharmaceuticals, Inc., increased the price for another injectable product by 95% in September 2014.⁵ Despite the existence of patient assistance and donation programs, these price increases complicate the goal of boosting the availability of naloxone,

¹ Senate Committee on Finance, *Hearing on Tackling Opioid and Substance Use Disorders in Medicare, Medicaid, and Human Services Programs*, 115th Cong. (Apr. 19, 2018) (S. Hrg. 115-XXX).

² *Id.*

³ At a hearing of the Committee on Homeland Security and Governmental Affairs on August 21, 2018, Centers for Medicare and Medicaid Services Administrator Seema Verma could not confirm whether outreach to Kaléo Pharma concerning naloxone price increases had occurred. *See* Senate Committee on Homeland Security and Governmental Affairs, *Hearing on Examining CMS's Efforts to Fight Medicaid Fraud and Overpayments*, 115th Cong. (Aug. 21, 2018) (S. Hrg. 115-XXX).

⁴ Ravi Gupta, et al., *The Rising Price of Naloxone—Risks to Efforts to Stem Overdose Deaths*, *New England Journal of Medicine* (Dec. 8, 2016) (www.nejm.org/doi/full/10.1056/NEJMp1609578).

⁵ *Id.*

which U.S. Surgeon General Dr. Jerome M. Adams has described as “a critical component of our efforts to reduce opioid-related overdose deaths.”⁶

These price increases can also impose significant costs on federal health programs. According to the Centers for Medicare and Medicaid Services, average Medicare Part D spending per dosage unit on Evzio increased by over 500% between 2015 and 2016, with total 2016 spending totaling more than \$40 million.⁷ Perhaps in recognition of these costs, the President’s Commission on Combating Drug Addiction and the Opioid Crisis recommended that the HHS Secretary be empowered to negotiate reduced pricing for governmental units of naloxone.⁸ In fact, according to the *Washington Post*, the Department of Veterans Affairs pays “far, far less” than the list price for Evzio—precisely because “the agency is legally authorized to negotiate with pharmaceutical companies.”⁹ To date, however, I am not aware of any actions from HHS to negotiate reduced pricing for Evzio or any other naloxone product.

To aid the Committee in understanding HHS’ efforts to combat rising costs for naloxone and ensure the availability of this lifesaving overdose reversal drug, please provide the following information:

1. Any actions HHS has taken, in response to my April 2018 request, to demand explanations from naloxone manufacturers concerning price increases;
2. Any actions HHS has taken to empower the HHS Secretary to negotiate reduced pricing for governmental units of naloxone; and
3. Any other actions HHS has taken to reduce federal expenditures on naloxone or expand access to naloxone for law enforcement officials and other first responders.

Please provide the requested information as soon as possible, but in no event later than September 25, 2018. If you have any questions related to this request, please contact Brandon Reavis of the Committee staff at Brandon_Reavis@hsgac.senate.gov or (202) 224-2627. Please send any official correspondence relating to this request to Rina_Patel@hsgac.senate.gov.

⁶ U.S. Surgeon General Dr. Jerome M. Adams, *Surgeon General’s Advisory on Naloxone and Opioid Overdose* (Apr. 5, 2018) (www.surgeongeneral.gov/priorities/opioid-overdose-prevention/naloxone-advisory.html).

⁷ Centers for Medicare and Medicaid Services, Medicare Part D Drug Spending Dashboard & Data (www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html) (accessed Aug. 20, 2018).

⁸ The President’s Commission on Combating Drug Addiction and the Opioid Crisis, *Final Report* (Nov. 1, 2017).

⁹ *The \$4,500 Injection to Stop Heroin Overdoses*, *Washington Post* (Jan. 27, 2017) (www.washingtonpost.com/business/the-4500-injection-to-stop-heroin-overdoses/2017/01/27/becaaca4-dcf6-11e6-ad42-f3375f271c9c_story.html).

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Sincerely,

A handwritten signature in blue ink that reads "Claire McCaskill". The signature is fluid and cursive, with the first name "Claire" starting with a large loop and the last name "McCaskill" following in a similar style.

Claire McCaskill
Ranking Member

cc: Ron Johnson
Chairman