

United States Senate

WASHINGTON, DC 20510

February 8, 2017

Mr. Spencer Williamson
President and Chief Executive Officer
Kaléo Pharmaceuticals
111 Virginia Street, Suite 300
Richmond, VA 23219

Dear Mr. Williamson:

We are deeply concerned about reports that Kaléo dramatically increased the cost of its naloxone injector device, Evzio, an FDA approved medication used for the emergency treatment of an opioid overdose—from \$690 for a two pack in 2014 to \$4,500 today. This drug is now in the hands of first responders and families struggling with substance use disorder across the country. It is particularly needed in rural areas where access to life-saving emergency services can be limited. Such a steep rise in the cost of this drug threatens to price-out families and communities that depend on naloxone to save lives.

Addiction to heroin and other opioids has reached epidemic levels. More than 30,000 Americans are estimated to die each year due to opioid overdoses. Through increased access to community education, treatment and recovery programs, so many of these deaths could be preventable. Naloxone products are an important part of any community's response to our nation's opioid crisis, and demand for naloxone products has increased significantly in recent years. Evzio was designed to be simple to administer, making it particularly well suited for use by laypersons such as families looking to protect loved ones from overdose. Unfortunately, reports indicate Kaléo has responded to the increased need for naloxone devices by ratcheting up the price for Evzio.

At a time when Congress has worked to expand access to naloxone products and to assist state and local communities to equip first responders with this life-saving drug, this startling price hike is very concerning. In response to press reports about the price increase, Kaléo has argued that the list price is not a "true gauge" for what consumers are actually paying for the device, because through program discounts and coupons patients often have a low or even zero cost share for Evzio. We are concerned about the impact the high list price may have for those who do not qualify for the program and for state and local entities who hope to purchase large quantities of your product.

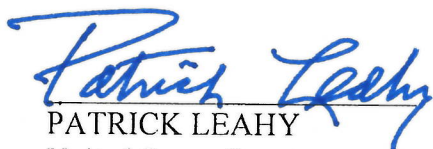
To help us understand Kaléo's actions, we would appreciate your response to the following:

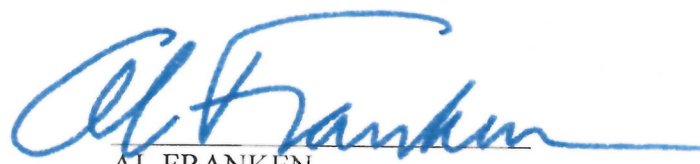
1. Please detail your pricing structure for Evzio since the product received FDA approval and provide documentation for why the company has chosen to adjust the pricing structure, including information on if the production costs of Evzio contribute to the price increases.

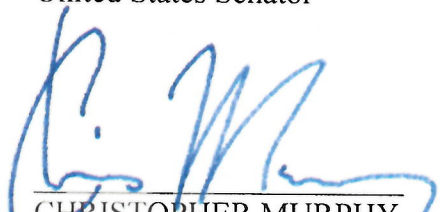
2. How many devices does Kaléo set aside for your donation program compared to your total production and how are you ensuring that it meets the demand for devices among first responders, state health departments, and other public entities across the country? Please explain what steps Kaléo has taken to inform consumers of their eligibility for these donation programs.
3. What is the total amount Evzio received in reimbursements from the federal government in the past 12 months? Approximately what percentage of your customers relied on federally funded dollars, through reimbursements or otherwise, to purchase Evzio during that period?

We look forward to working with you to ensure patients across the country have access to this life-saving device.

Sincerely,


PATRICK LEAHY
United States Senator

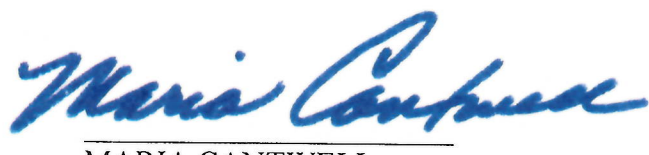

AL FRANKEN
United States Senator

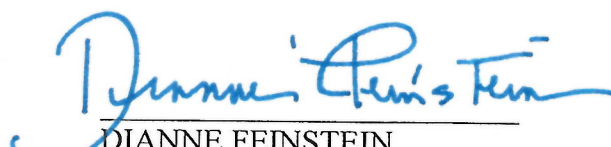

CHRISTOPHER MURPHY
United States Senator

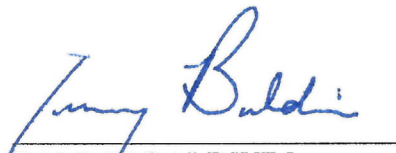

JACK REED
United States Senator

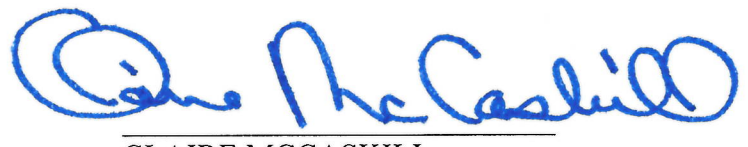

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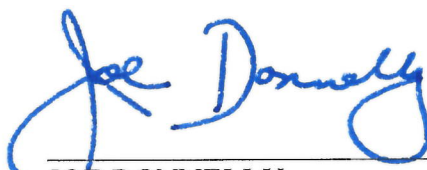

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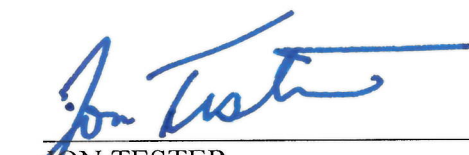

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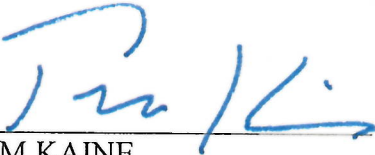
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TIM KAINE
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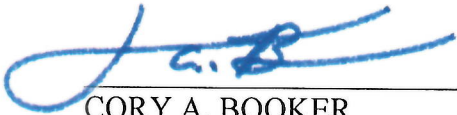
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