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United States Senate

SPECIAL COMMITTEE ON AGING

WASHINGTON, DC 20510-6400

(202) 224-5364

June 3, 2016

Mr. Spencer Williamson
President and CEO
Kaléo Pharma
111 Virginia Street, Suite 300
Richmond, VA 23219

Dear Mr. Williamson:

The prescription drug abuse and heroin crisis has reached epidemic proportions across the United States and is overwhelming our families and communities with tragic consequences. The Centers for Disease Control and Prevention (CDC) reported more than 27,000 overdose deaths involving prescription opioid medications, heroin, or both in 2014. This troubling statistic might have been even higher if not for the use of naloxone, a critically important drug used to reverse opioid overdoses for the last 45 years. Our states are both deeply affected by this crisis. Maine experienced 272 overdose deaths from heroin and other substances in 2015, a dramatic increase from the 16 deaths in 2010. In Missouri, the number of accidental drug poisoning deaths involving heroin climbed to 338 in 2014, nearly double the number in 2010.

As we work to address a complex public health crisis, it is important that naloxone, a potentially lifesaving tool, be accessible. Particularly in rural states, it is not uncommon that those responding to opioid overdoses are police officers, fire fighters, and family members rather than medical personnel.

Congress is working to combat the opioid and heroin epidemic through a multi-faceted approach that includes education, treatment, and law enforcement. As one component of this effort, Congress provided funding to help first responders acquire products—including naloxone—to reverse overdose and provide training in their use. We are concerned, therefore, by recent news reports that indicate the rising price for naloxone may be limiting access for emergency responders and public health departments. A *Politico* article noted that the price of at least one version of the drug reportedly rose 17-fold in the last two years, which could limit the reach of federal programs designed to support its expanded use. In addition, *Healthline* stated that hospitals have also reported difficulty obtaining sufficient quantities of the drug, especially as repeated doses are sometimes needed to keep up with illicit opioids that are growing in potency.

Given these reports, we request that you provide insight into what actions you are taking to ensure continued and improved access to naloxone, an explanation for price changes in your company's naloxone product, and a description of the available resources and tools to prevent barriers to access and shortages of this critical and life-saving medication.

Naloxone alone will not solve our addiction crisis, but remains critical during emergencies. We look forward to your response and to learning what steps Kaléo is taking to help ensure that our communities have access to naloxone. Please respond to this inquiry no later than June 23, 2016. Should you have any questions, please have your staff contact Olivia Kurtz of the Majority staff at 202-224-5364 or Phylicia Woods of the Minority staff at 202-228-3771.

Sincerely,



Susan M. Collins
Chairman



Claire McCaskill
Ranking Member