

Congress of the United States
Washington, DC 20515

February 21, 2017

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

Dear Mr. Williamson:

We write to ask for answers to recent 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. As members of congress who have seen firsthand the toll the opioid epidemic has taken on our communities, we cannot sit idly by while life-saving naloxone is priced beyond reach of those that need it.

More than 30,000 Americans are estimated to die each year due to opioid overdoses but naloxone, if administered in time, can reverse the overdose effects of opioids. 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. As you no doubt understand, naloxone products are an important part of any community's response to our nation's opioid crisis, and demand for naloxone products has sadly increased significantly in recent years.

Unfortunately, reports indicate Kaléo has responded to the increased need for naloxone devices by raising the price for Evzio by over 600%. 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 program discounts and coupons often leave patients with a low or even zero out-of-pocket cost 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.

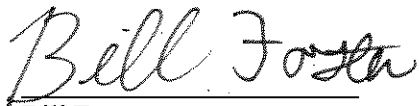
To help us understand Kaléo's actions, we would appreciate your response to the following questions which our Senate colleagues have also asked you:

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 any changes to the cost of production of Evzio.
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,



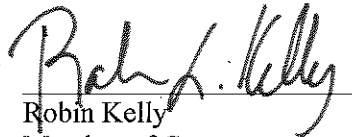
Bill Foster
Member of Congress



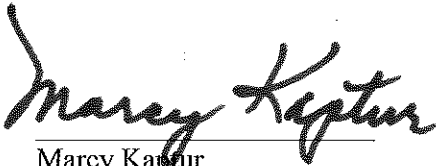
Tim Ryan
Member of Congress



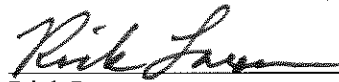
Gwen Moore
Member of Congress



Robin Kelly
Member of Congress




Marcy Kaptur
Member of Congress



Rick Larsen
Member of Congress



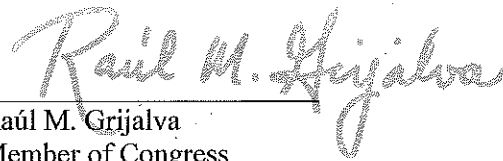
Bobby Rush
Member of Congress



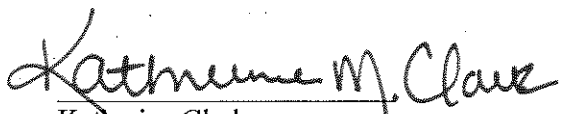
Donald Norcross
Member of Congress

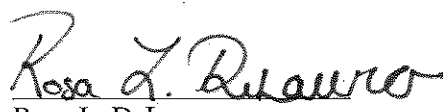


Jim Langevin
Member of Congress

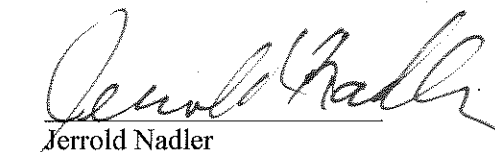


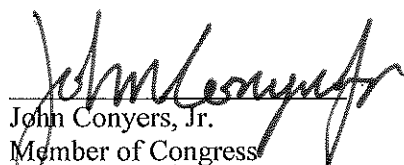
Raúl M. Grijalva
Member of Congress

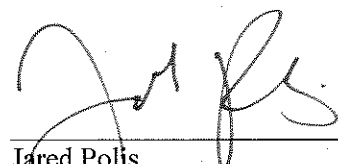

Katherine Clark
Member of Congress

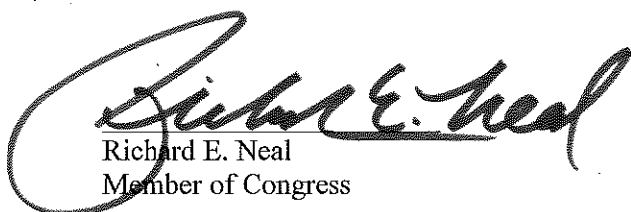

Rosa L. DeLauro
Member of Congress



Lloyd Doggett
Member of Congress



Jerrold Nadler
Member of Congress


John Conyers, Jr.
Member of Congress

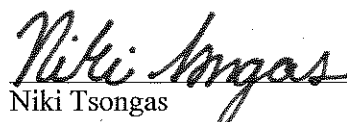

Jared Polis
Member of Congress

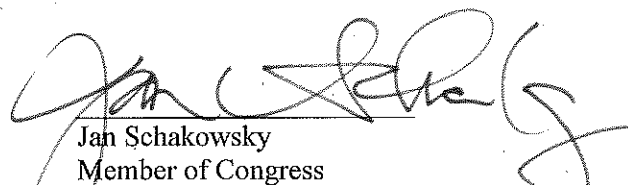

Richard E. Neal
Member of Congress

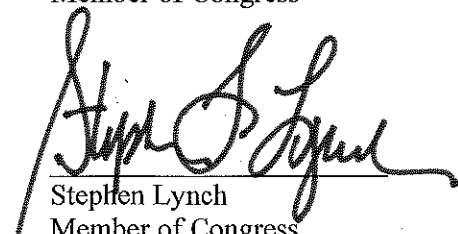

William R. Keating
Member of Congress



Mark Pocan
Member of Congress


Ann McLane Kuster
Member of Congress


Niki Tsongas
Member of Congress


Jan Schakowsky
Member of Congress


Stephen Lynch
Member of Congress


Sean Patrick Maloney
Member of Congress



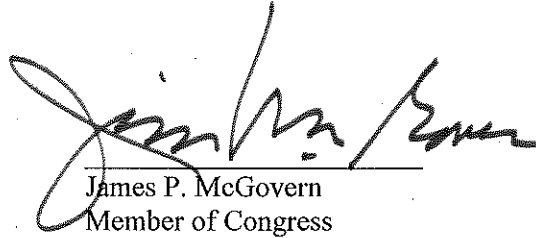
Earl Blumenauer
Member of Congress



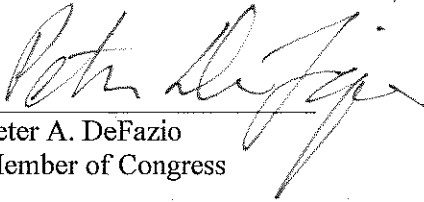
Carol Shea-Porter
Member of Congress



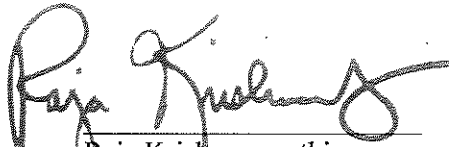
Debbie Dingell
Member of Congress



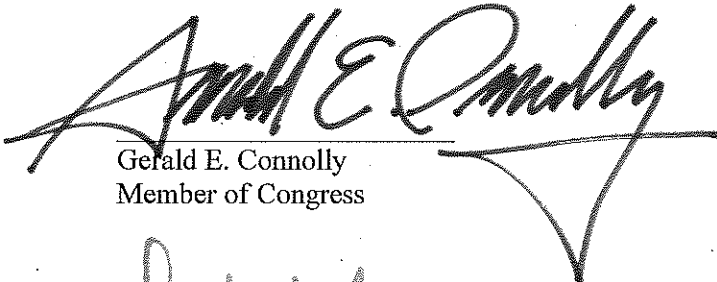
James P. McGovern
Member of Congress



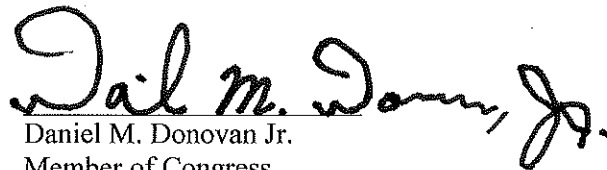
Peter A. DeFazio
Member of Congress



Raja Krishnamoorthi
Member of Congress



Gerald E. Connolly
Member of Congress



Daniel M. Donovan Jr.
Member of Congress



Seth Moulton
Member of Congress



Daniel W. Lipinski
Member of Congress




Cheri Bustos
Member of Congress



Kurt Schrader
Member of Congress



Denny Heck
Member of Congress



Brenda L. Lawrence
Member of Congress

Danny K. Davis

Danny K. Davis
Member of Congress

Joseph P. Kennedy, III

Joseph P. Kennedy, III
Member of Congress

Michelle Lujan Grisham John P. Sarbanes

Michelle Lujan Grisham
Member of Congress

John Sarbanes
Member of Congress

Collin C. Peterson

Collin C. Peterson
Member of Congress

Eleanor H. Norton

Eleanor Holmes Norton
Member of Congress

Dave Loebsack

Dave Loebsack
Member of Congress

Luis V. Gutiérrez

Luis V. Gutiérrez
Member of Congress

Grace F. Napolitano

Grace F. Napolitano
Member of Congress

David N. Cicilline

David N. Cicilline
Member of Congress

Bradley S. Schneider

Bradley S. Schneider
Member of Congress

Sander M. Levin

Sander M. Levin
Member of Congress

Chellie Pingree

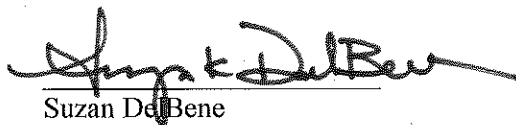
Chellie Pingree
Member of Congress

Steve Cohen

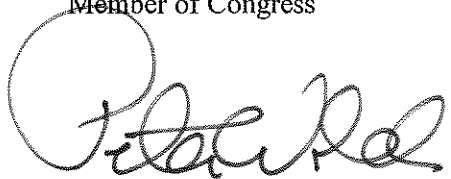
Steve Cohen
Member of Congress



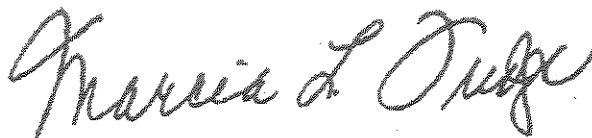
Derek Kilmer
Member of Congress



Suzan DelBene
Member of Congress




Peter Welch
Member of Congress



Marcia L. Fudge
Member of Congress



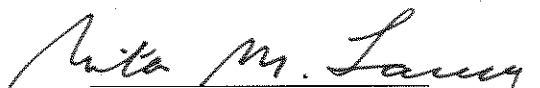
Nanette Diaz Barragan
Member of Congress



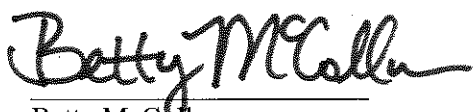
José E. Serrano
Member of Congress



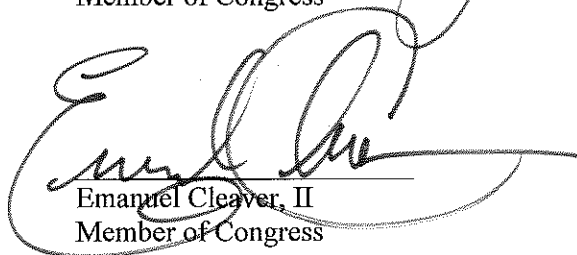
Paul D. Tonko
Member of Congress



Nita Lowey
Member of Congress



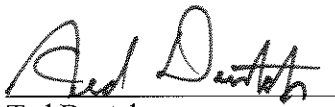
Betty McCollum
Member of Congress



Emanuel Cleaver, II
Member of Congress



John Yarmuth
Member of Congress



Ted Deutch
Member of Congress



Mike Doyle
Member of Congress



Lois Frankel
Member of Congress

Daniel T. Kildee

Dan Kildee
Member of Congress

Zoe Lofgren

Zoe Lofgren
Member of Congress

Donald S. Beyer Jr.

Donald S. Beyer Jr.
Member of Congress

Suzanne Bonamici

Suzanne Bonamici
Member of Congress

Joe Courtney

Joe Courtney
Member of Congress

Ben Ray Lujan

Ben Ray Luján
Member of Congress