

## Durbin, Duckworth demand answers about outrageous price hike for lifesaving anti-opioid drug

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WASHINGTON – U.S. Senators Dick Durbin (D-IL) and Tammy Duckworth (D-IL) are among a group of 31 Senators that are demanding answers from a leading pharmaceutical company about the dramatic price hike for a life-saving medication used to respond to opioid overdoses.

Recent reports <u>unveiled</u> that drug maker Kaléo Pharmaceuticals, which manufactures an easy-to-use injector device containing the overdose-reversing drug naloxone, raised its price from \$690 in 2014, to \$4,500 currently. While the Evzio device has the potential to help thousands of individuals survive drug overdoses, the Senators wrote that the inexplicable price hike "threatens to price-out families and communities that depend on naloxone to save lives."

"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," the Senators <u>wrote</u> Wednesday to Kaléo Pharmaceuticals CEO Spencer Williamson.

The bipartisan Comprehensive Addiction and Recovery Act (CARA), which was signed into law last year with Durbin and Duckworth's support, includes a provision to help rural communities obtain the overdose-reversing drug Naloxone. Rural locations have the <u>highest death rates in the country</u> from opioid poisoning, and Naloxone has the potential to save more lives in these areas.

In addition to Senators Durbin and Duckworth, the letter was signed by Senators Patrick Leahy (D-VT), Al Franken (D-MN), Christopher Murphy (D-CT), Jack Reed (D-RI), Sheldon Whitehouse (D-RI), Maria Cantwell (D-WA), Dianne Feinstein (D-CA), Tammy Baldwin (D-WI), Claire McCaskill (D-MO), Jeanne Shaheen (D-NH), Angus King (I-ME), Richard Blumenthal (D-CT), Edward J. Markey (D-MA), Maggie Hassan (D-NH), Amy Klobuchar (D-MN), Heidi Heitkamp (D-ND), Elizabeth Warren (D-MA), Kirsten Gillibrand (D-NY), Joe Donnelly (D-IN), Jon Tester (D-MT), Bernie Sanders (I-VT), Sherrod Brown (D-OH), Debbie Stabenow (D-MI), Tom Udall (D-NM), Tim Kaine (D-VA), Mark Warner, (D-VA), Gary Peters (D-MI), Jeff Merkley (D-OR), and Cory Booker (D-NJ).

A copy of the February 8 letter to Kaléo Pharmaceuticals is available <u>online</u> and below.

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.