

United States Senate
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
Committee on Homeland Security and Governmental Affairs

Rob Portman, Chairman
Tom Carper, Ranking Member

**COMBATTING THE OPIOID CRISIS:
THE PRICE INCREASE OF AN OPIOID
OVERDOSE REVERSAL DRUG AND THE COST
TO THE U.S. HEALTH CARE SYSTEM**

STAFF REPORT

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COMBATTING THE OPIOID CRISIS: THE PRICE INCREASE OF AN OPIOID OVERDOSE REVERSAL DRUG AND THE COST TO THE U.S. HEALTH CARE SYSTEM

EXECUTIVE SUMMARY

Over the last four years, the Subcommittee has conducted several extensive investigations on the opioid epidemic and the federal government’s response to the crisis. As part of that broader effort to examine the opioid crisis and its impact on the American people, the Subcommittee conducted a case study investigation into the cost of naloxone, the prescription drug used to revive individuals who overdose on opioids. This report documents the Subcommittee’s findings from that investigation, and specifically how one pharmaceutical company – kaleo, Inc. – exploited the opioid crisis by increasing the price of its naloxone drug EVZIO by more than 600 percent (from an initial price of \$575 per unit to \$3,750 and then \$4,100 eleven months later), resulting in more than \$142 million in charges to taxpayers in just the last four years.

Kaléo raised the price of EVZIO in February 2016 and launched its new distribution model planning to “[c]apitalize on the opportunity” of “opioid overdose at epidemic levels” and a “well established public health crisis.” As part of its new distribution model, the company’s sales force focused on ensuring doctor offices signed any necessary paperwork (called prior authorizations) for the EVZIO prescription to be filled and covered. This included paperwork indicating that EVZIO was medically necessary, which ensured the drug would be covered by government programs like Medicare and Medicaid for the Wholesale Acquisition Cost, less any patient copays, despite the fact that less costly alternatives exist.

* * * * *

The opioid crisis continues to grip our country. The Department of Health and Human Services’ 2018 National Survey on Drug Use and Health found that 11.4 million Americans misused opioids last year, while 2.1 million Americans suffered from opioid disorders. At the same time, the Centers for Disease Control and Prevention (“CDC”) found that 72,000 Americans died from drug overdoses in 2017 – more overdose deaths in just one year than the total number of American casualties during the entire Vietnam War. The majority of those overdose deaths—49,068 individuals or 68 percent—involved opioids.

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