

*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**

**PERMANENT SUBCOMMITTEE ON  
INVESTIGATIONS**

**UNITED STATES SENATE**



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

**TABLE OF CONTENTS**

EXECUTIVE SUMMARY .....	1
The Subcommittee’s Past Investigations .....	6
Findings of Fact and Recommendations .....	8
I.    BACKGROUND .....	12
A. The Opioid Epidemic .....	12
1. Deaths from Opioid Overdoses .....	13
2. Economic Toll of the Opioid Crisis .....	14
3. Prescription Opioids.....	14
4. The Rise of Illicit Opioids .....	15
i. Heroin .....	16
ii. Fentanyl and Other Illicit Synthetic Opioids.....	17
B. The Role of Naloxone .....	18
1. Development and FDA Approval of Naloxone .....	18
2. Naloxone Administration.....	19
3. Naloxone Brand Names .....	20
i. Kaleo, Inc.’s EVZIO .....	20
ii. Adapt Pharma’s Narcan.....	22
iii. Generic Naloxone .....	22
C. The Commercial Health Care Market in the United States.....	23
1. Patient Assistance Programs and Coupons .....	24
2. Pharmacy Benefit Managers .....	24
3. Federal Government Funded Health Care Programs .....	26
i. Medicare Part D .....	27
ii. Medicaid.....	28
iii. The Department of Veterans Affairs .....	29

iv. The Department of Defense and TRICARE .....	30
II. KALÉO DEVELOPED THE FIRST TAKE-HOME NALOXONE AUTO-INJECTOR FOR OPIOID OVERDOSE.....	32
A. Kaléo Developed an Auto-injector for Naloxone and Branded the Product as “EVZIO” .....	32
B. Kaléo Set the Initial Price of EVZIO at \$575 .....	33
C. Kaléo Commissioned Outside Pricing Studies for EVZIO .....	37
1. Two Pricing Consultants Advised Kaléo to Price EVZIO around \$300 and Offer Additional Discounts .....	37
2. Kaléo Commissioned a Study for Pricing EVZIO at \$575.....	39
D. Kaléo Contracted with Pharmacy Benefit Managers to Sell EVZIO .....	42
1. Express Scripts.....	43
2. CVS Caremark .....	45
III. KALEO INCREASED THE WHOLESALE ACQUISITION COST OF EVZIO FROM \$575 TO \$3,750 AND CHANGED ITS DISTRIBUTION MODEL.....	46
A. Kaléo Increased the Price of EVZIO from \$575 to \$750 .....	46
B. Kaléo Hired Consultants Todd Smith and Ben Bove to Change its Distribution Model.....	47
1. The Distribution and Pricing Model used by Horizon.....	47
2. Messrs. Smith and Bove Established Novum Pharma.....	49
C. Kaléo Hired Messrs. Smith and Bove to Change the Way EVZIO Is Distributed .....	50
1. Kaléo established a pilot program for the new distribution model.....	50
2. Kaléo Cited Barriers to EVZIO in the Traditional Pharmaceutical Market.....	52
D. The Kaléo Board of Directors Approved Moving to the New Distribution Model..	53
E. The Elements of Kaléo’s New Distribution Model for EVZIO .....	54
1. Kaléo Increased the Price of EVZIO to \$3,750 .....	56
2. Kaléo Increased EVZIO’s Price to \$4,100 When it Launched EVZIO 2.0 mg .....	57
3. The Distribution Model Sought to Reduce the Prior Authorization Paperwork Burden on Health Care Providers.....	58
4. Kaléo Used a Hub for a Portion of its Prescriptions through the New Distribution Model.....	60

F. The Number of Prescriptions Filled for EVZIO Increased .....	61
I. Messrs. Smith and Bove were Compensated Based on the Success of the Distribution Model they Helped Install.....	62
G. Kaléo Ended its Relationship with Messrs. Smith and Bove .....	65
IV. PHARMACY BENEFIT MANAGERS RESPONDED TO KALEO'S PRICE INCREASE BY EXCLUDING EVZIO FROM FORMULARIES .....	66
A. CVS Added Narcan to its Formulary and Ended Coverage of EVZIO .....	66
B. Express Scripts Allowed Plans to Impose a Cheaper Alternative to EVZIO and Then Replaced it with Narcan .....	68
1. Express Scripts Allowed its Member Plans to Impose Step Edits before a Patient Received an EVZIO.....	68
2. Express Scripts Excluded EVZIO from its Formulary .....	70
3. Express Scripts Sued Kaléo.....	70
4. Kaléo's Payments to Express Scripts .....	71
V. THE COST OF KALÉO'S PRICE INCREASE ON GOVERNMENT FUNDED PRESCRIPTION DRUG PROGRAMS .....	74
A. Medicare Part D.....	74
B. Medicaid.....	78
C. Department of Veterans Affairs.....	82
D. Department of Defense TRICARE Health Care Program .....	83
VI. CONCLUSION.....	85
ANNEX.....	86

# 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.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.