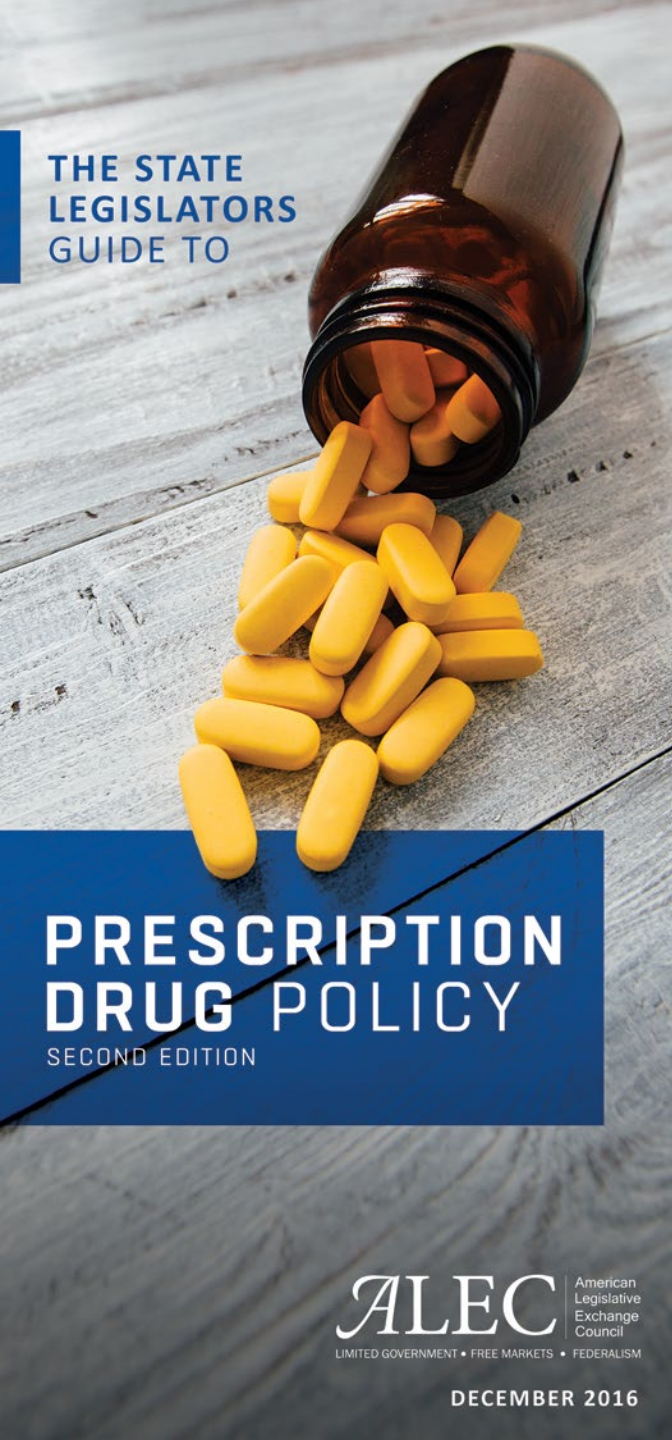


THE STATE LEGISLATORS GUIDE TO

PRESCRIPTION DRUG POLICY

SECOND EDITION

ALEC American Legislative Exchange Council

LIMITED GOVERNMENT • FREE MARKETS • FEDERALISM

DECEMBER 2016

TABLE OF CONTENTS

ABOUT ALEC

The American Legislative Exchange Council (ALEC) is a 501(c) 3 nonprofit organization and is the largest nonpartisan, voluntary membership organization of state legislators in the United States dedicated to the principles of limited government, free markets and federalism. The Council is governed by state legislators who comprise the National Board of Legislators and is advised by the Private Enterprise Advisory Council, a group of private, foundation and think tank members.

ABOUT THIS GUIDE

There has been a recent public outcry about the high cost of healthcare in the United States, with prescription drug prices at the center of the debate. As a result, proposals calling for price caps on brand and specialty medicines are gaining popularity as a solution to bring down the cost of care. As with most government intervention, this approach will have the stifling effect of reducing patient access to prescription drugs, while also slowing the development of innovative new therapies for both chronic and rare disease over time.

This Guide is a primer for elected officials who wish to learn more about prescription drug policy, limit government overreach, and encourage free-market solutions so the U.S. may remain a pioneer in the development of new prescription treatments and cures. The pages ahead will outline key aspects impacting prescription drug policy and provide recommendations for lawmakers weighing legislative action that will affect the development of and patient access to medicine.


PRESCRIPTION

Introduction

The U.S. biopharmaceutical industry is the single largest contributor to the development of innovative and life-saving medicines that prevent, treat, and cure disease. This has been proven through the immense progress in cancer survival rates[i] and the emergence of managing what were once life-threatening diseases such as HIV/AIDS and curing Hepatitis C with medicines, not invasive surgery or costly hospital care.

While scientific advancements are moving us forward, the administration of healthcare in the U.S. continues to change. With the implementation of the Affordable Care Act (ACA), healthcare providers have taken on a staggering level of new regulatory requirements, impacting all aspects of how patients receive and pay for care.

Whether you have employer-sponsored health insurance or an insurance policy purchased through a healthcare marketplace, the cost of care has been slowly shifting to the patient, particularly in the case of prescription and specialty drugs. As a result, legislative and ballot action limiting what payers can pay for new and innovative therapies are being considered at both the state and federal level, which, if enacted will limit access to innovative drug therapies, as is the case[ii] in the United Kingdom (U.K.).

This Guide outlines the impact continued research and development (R&D) investment for new medicines will have on the future of healthcare in the U.S., as well as key topics affecting prescription drug pricing. With this background lawmakers can make better informed decisions when considering legislative or regulatory action surrounding prescription drug policy.

Prescription Drugs in the U.S.

On average, developing a prescription innovation takes 10 years, and requires upwards of $2.6 billion dollars in investment. The process of discovery is fraught with challenge, and only 12 percent of medicines in development reach the market. Despite this, researchers use knowledge learned through failure to reach scientific breakthroughs in pharmaceutical innovation.

BETWEEN 1998 AND 2014

There were **123** medicines in R&D for alzheimer's disease. **Only 4 reached the market.**

There were **96** medicines in R&D for melanoma. **Only 7 reached the market.**

There were **167** medicines in R&D for lung cancer. **Only 10 reached the market.**

The Institute for Healthcare Informatics reports 89 percent of all prescriptions filled in 2015 were filled with generic drugs.[iii] This is crucial when considering private investment from past medical breakthroughs is part of the lifecycle of patents for prescription innovations. Some important points include:

- The Centers for Disease Control (CDC) National Health Expenditures data[iv] shows spending on prescription drugs is just 10 percent of all healthcare spending in the U.S.
- There are currently 7,000 new therapies in development, many of which have the potential to revolutionize how we treat both rare and chronic disease.

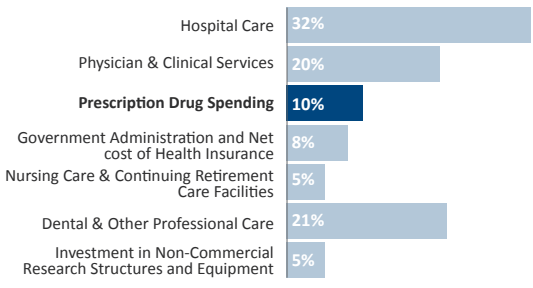
- Seventy percent of new prescription innovations are potentially first-in-class, or a completely new way to approach treating or preventing a disease or chronic condition.
- More prescription treatment options will prevent the need for expensive surgery and hospitalization, resulting in increased quality of life and greater cost savings in healthcare.

POLICY RECOMMENDATION: Allow free-market competition to determine the price of prescription drugs; government regulation of prescription drug prices will result in slowing the discovery of future prescription innovations.

Healthcare Spending in the U.S.

Major drivers of healthcare spending in the U.S. can be broken into the following categories, hospital care, physician and clinical spending, health insurance administration and pharmaceuticals. However, over half of all healthcare spending is comprised of hospital, physician and clinical care. Pharmaceuticals represent only 10 percent of total spending (see Figure 1).

Figure 1



**Numbers may not add up due to rounding.*

The year 2014 was an abnormal year for healthcare spending. It was the first year major provisions of ACA implementation, including the state-based Marketplace Exchanges, as well as Medicaid Expansion, providing health coverage to previously uninsured populations which resulted in a spike in healthcare utilization. It was also the year the first prescription drug cure for the often fatal and costly Hepatitis C virus came to market. While the breakthrough drug's initial list price was high, the entrance of competitor brand drugs allowed the spending curve on prescription drugs to normalize in 2015 and 2016[v].

According to the PricewaterhouseCoopers Health Research Institute 2017 Medical Cost Trend Report[vi], healthcare spending will be a 'year of equilibrium' for medical costs in the U.S. Trends such as increased access to care through retail health clinics and behavioral health services will increase the cost of healthcare, while greater usage of high performance networks, aggressive negotiating tactics by pharmacy benefit managers (PBMs) and the leveling off of new specialty drugs entering the market will keep healthcare spending in the U.S. on par with current levels.

What We Have Learned From the Hepatitis C Cure

In December 2013, the first Hepatitis C prescription cure came to market. In its initial release the treatment was priced at $1,000 per pill, which amounted to $84,000 for one course of the treatment. Within 12 months, a second Hepatitis C cure was approved by the Food and Drug Administration (FDA), allowing PBMs to leverage competitive market forces with prescription drug makers to significantly reduce the final price paid. In just one year, the price declined as much as 46 percent[vii].

Biopharmaceutical companies race to bring breakthrough drugs to market, and often, when the FDA approves one prescription drug another medicine to treat the same condition is close behind.

The Hepatitis C prescription cure – which has an over 90 percent success rate – saves patients from a series of costly medical events including treating liver disease, liver cancer, and cirrhosis of the liver, which could result in hospitalizations and surgeries ranging from $59,995 to as much as $500,000 for a liver transplant[viii]. For patients who have been treated with the new Hepatitis C treatments the reduction in medical events caused by the virus will result in downstream cost savings in health utilization, along with an increase in productivity for patients over the long term.

Pharmacy Benefit Manager's Role in Prescription Drug Pricing

In the healthcare industry, PBMs serve as a middleman who negotiates with prescription drug manufacturers on behalf of payers, which can include commercial health insurers, employers, Medicaid Managed Care Organizations, state and federal government employee plans, Medicare Part D drug plans, and others. In 2016, PBMs negotiated the price for prescription drugs for 266 million Americans[ix] for brand and specialty medications.

When there is more than one prescription drug available to treat a medical condition, PBMs will use their purchasing power to negotiate significant cost savings, which on average is an 18 – 19 percent rebate granted by drug companies. Through the use of PBMs, there has been reported savings totaling nearly $350 billion[x] dollars on prescription drugs in the U.S. in 2016 alone.

While PBMs reduce costs for payers, this reduction is often not realized by consumers who pay co-insurance based on the list price, not the negotiated price, of a prescription drug. The issue of drug pricing is further complicated by the interchangeable use of 'list price' and 'net price' when reporting on prescription drug spending to the public.

- The 'list price' for a prescription drug is the price PBMs and drug manufacturers start at to negotiate the final price paid for a drug.
- The 'net price' for a prescription drug is what a drug manufacturer is paid after discounts and rebates have been realized.
- Drug manufacturers negotiate steep discounts with PBMs to be included on a prescription drug formulary or preferred drug list.

POLICY RECOMMENDATION: Elected officials should allow industry leaders to leverage purchasing power through competitive market forces, and resist government mandated price controls on prescription drugs.

Prescription Drug Formularies and Preferred Drug Lists

In the U.S., annually approved drug lists are used to determine what prescription drugs will be covered by payers, and are referenced in different ways for different types of healthcare coverage.

- A prescription drug formulary is a list of prescription drugs that will be paid for by a payer such as a health insurer or public program such as Medicare or Medicaid.

- A preferred drug list is a list of prescription drugs approved for Medicaid beneficiaries, typically determined by an independent committee of healthcare professionals.

With the implementation of the ACA, health insurers are more frequently designing prescription drug formularies that have four, five, or more tiers, with lower tiers comprised of low-cost generics and higher tiers comprised of newer brand name and specialty drugs. Recently, there have been formularies with all drugs in a class, such as those for HIV/AIDS[xi] and cancer, being placed exclusively on higher tiers.

Each tier of a drug formulary will have different levels of patient cost sharing, and often include co-pays, co-insurance, a separate deductible for prescription drugs, or use a combination of these. This has resulted in insurers passing much of the cost of the more expensive prescription and specialty drugs on to patients.

For instance in 2016, 75 percent of Marketplace Exchange silver plans – which are health plans with the highest-enrollment – required patients to pay their entire deductible for specialty drugs before their insurer begins sharing the cost of care[xii]. This level of cost-sharing deters patients from maintaining their prescription treatments which often leads to increased healthcare utilization through physician and hospital care. On average, 17 percent of cost sharing for prescription drugs is passed on to patients, as opposed to four percent of the cost of a hospitalization[xiii].

POLICY RECOMMENDATION: Incentivize payers to ensure patient access to prescription drugs on higher tiers of a drug formulary are not out of financial reach.

Medicines Will Play a Critical Role in Controlling Future Healthcare Costs

As more prescription drug breakthroughs come to market, their role in the way we manage disease will improve both quality of life and life expectancy for patients. It is well documented that patients who have very high co-pays, co-insurance, or deductibles for their medicines have less success adhering to the prescribed dosage of their prescription drugs over the long term, and cause patients to engage in pill-splitting, or missing doses to conserve pills and keep costs down. Some findings on this include:

- A National Bureau of Economic Research study on the Medicare Part D program determined hospitalizations decreased eight percent when the patient has prescription drug coverage[xiv].
- A Manhattan Institute report showed the benefit of prescription drugs for patients and the healthcare industry is monetized at $4 trillion dollars[xv] in cost savings, and also resulted in less utilization of healthcare (e.g., hospitalizations) over time.
- The IMS Institute for Healthcare Informatics recently reported the U.S. healthcare system could save $213 billion annually, if medicines were used properly[xvi].

POLICY RECOMMENDATION: Incentivize payers to encourage patient adherence to prescription drugs, particularly for chronically ill patients.

Medicaid and Prescription Drugs

Recent proposals to price-fix prescription drug prices are misleading, as mandatory rebates and supplemental discounts are in place and effective in creating cost savings for state budgets. The average spending level for prescription drugs in the Medicaid program account for only four to five percent of the entire Medicaid budget[xvii] and is expected to remain the same through 2023. In comparison, spending for hospital care is approximately three times this amount, and is forecasted to rise over time.

- The Medicaid program is statutorily mandated a prescription drug rebate of 23.1 percent of the Average Manufacturers Price (AMP) for brand and specialty drugs by Section 1927 of the Social Security Act.
- A larger rebate is paid by pharmaceutical manufacturers of brand and specialty drugs if their AMP increases more than inflation.
- In addition to the mandated rebate, Managed Care Organizations (MCOs) or state Medicaid programs will negotiate supplemental rebates, on average up to 60 percent off[xviii] the list price.
- Drug manufacturers offer steep discounts on brand name medicines so they will be included on the preferred drug list.
- Between 2010 and 2013, brand name drug companies granted $82.3 billion[xix] in rebates for prescription drugs sold to state Medicaid programs.

Rebates and discounts negotiated by states show existing competitive market forces are effective in reducing the price paid for prescription drugs, while encouraging innovation and development of new treatments and cures.

Price-Fixing Stifles Innovation and Competitive Market Forces

There has been recent legislative action and public discourse around the concept of restricting the price state and federal agencies can or will pay for prescription drugs, just as the Department of Veterans Affairs (VA) currently does. This approach will limit drugs available to patients, as well as result in the reduction of fewer prescription innovations over time.

Foreign countries that set the price of prescription drugs reduce patient access to cutting-edge pharmaceutical innovation. For instance, it has been reported the U.K.'s National Health System can take up to 9 years[xx] before adding breakthrough medicines to their approved drug list.

In addition to the threat price-fixing and disclosure requirements bring to the future of medical innovation, elected officials should consider the damage these policies will have on the marketplace. PBMs and biopharmaceutical manufacturers both agree competition in the market for prescription drugs will allow them to save the healthcare system up to $4 billion dollars a year, and further[xxi], will impose greater regulation on an already heavily regulated industry.

Policies requiring increased disclosure of proprietary information to regulators (often termed as transparency) will diffuse existing market-based strategies PBMs and payers rely on to negotiate discounts. It should also be noted that drug manufacturers are required to provide extensive information on the effectiveness of prescription drugs in order to gain FDA approval. On the financial side, cost, sales, and total R&D expenditures are reported in quarterly securities filings.

- When calculating risk, private investors analyze the return on their investment. If price-fixing prescription drugs becomes a strategy to curb the cost of healthcare in the U.S., less investment will be made in biopharmaceutical R&D.
- Recent efforts calling for greater transparency in the cost of developing prescription drugs do not include the costs associated with setbacks on the path to discovery of a new innovative medicine, which is critical to advancing the scientific process.
- Reporting proprietary business information on drug development to regulators will not benefit patients, and will have the unintended consequences of increasing administrative costs and red tape required to maintain compliance.
- It is the U.S. market-based system which leads the globe in allowing for the development of new life-saving treatments by drug manufacturers.

POLICY RECOMMENDATION: Create a regulatory environment that encourages greater collaboration on drug pricing between health insurers, PBMs and drug manufacturers.

Biopharmaceutical Investment in Research and Development

It has been suggested that much of the prescription drug development in the U.S. is attributed to research in academic institutions or conducted by the National Institutes of Health (NIH). While academia and the NIH play an important role in drug discovery, the U.S. biopharmaceutical industry invests nearly twice as much and carries

out critical pieces of research, development and manufacturing that cannot be replicated in the public sector (see Figure 2).

FIGURE 2

National Institutes of Health (NIH) **$30.6**[1] **billion** dollars in investment in 2015.

In 2015, the biopharmaceutical industry has invested **$58.8 billion**[1].

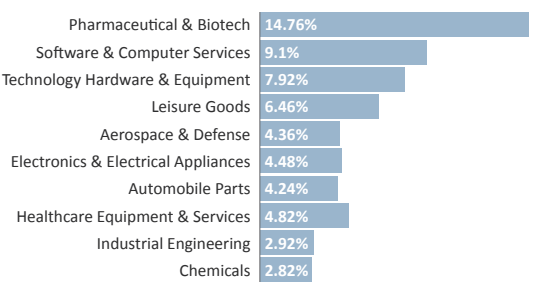
*Since 2000, U.S. biopharmaceutical companies have invested more than **$550 billion** dollars in the search for new treatments and cures.*

[1]*Tufts Center for the Study of Drug Development Public and Private Sector Contributions to the Research & Development of the Most Transformational Drugs of the Last 25 Years, R. Chakravarthy, K. Cotter, J. DiMasi, C. Milne, N. Wendel, January 2015. And National Institutes of Health Office of Budget 2016 Operating Plan, Accessed November 2016*

Economic Value of Biopharmaceutical Research & Development

Through its enormous investment, biopharmaceutical companies support over three million U.S. jobs, and are the largest investor of research and development of any other industry.

U.S. INDUSTRY SECTORS AVERAGE INVESTMENT IN R&D 2010 - 2014



Current Trajectory of Oncology Research

Unfortunately, almost everyone has been touched by cancer, and for many, breakthroughs in oncology research have not come to market quickly enough. However, according to a recent report by the IMS Institute for Healthcare Informatics, the pipeline and trajectory of oncology research medical science is on the cusp of a new wave of breakthrough cancer treatments[xxii].

Medical advancements made by progress in mapping the human genome have led to the emergence of personalized medicine. Personalized medicine uses diagnostic tools to identify genetic biomarkers so doctors may customize which treatments will be most effective for each patient.

- In the cancer drug pipeline 73 percent of medicines have the potential to be personalized medicines[xxiii].
- Cancer medicines account for only one percent of total healthcare spending in the U.S.
- Since 1991, the death rate for cancer patients has declined by 20 percent.
- New life-saving medicines available for cancer will allow more hope for recovery, longer life expectancy and greater productivity for cancer patients and their families.

The IMS Institute for Healthcare Informatics Global Outlook for Medicines Through 2018 recently reported "medicines [are] playing a more central role in the timely and cost-effective prevention of treatment and disease, helping to lower costs to health systems overall as patient outcomes and satisfaction can improve."

POLICY RECOMMENDATION: Discourage greater regulation of R&D investment in the discovery of new therapies; ensure payment reimbursement mechanisms are tied to patient outcomes.

Bad Actors Overshadow the Industry

Some pharmaceutical companies have been reported in the national media for engaging in business tactics that manipulate the market to create an artificial demand for their product. Exploitative actions such as these should be investigated for criminal action, as they currently are in the case of both Valeant and Turing Pharmaceuticals.

The difference between these companies and the majority of the biopharmaceutical industry is the level of investment pharmaceutical companies put back into R&D, in order to drive the discovery of new life-saving medicines. It is important to differentiate between bad actors and companies who are truly innovating and advancing medicine.

Importation and Counterfeit Pharmaceuticals

Prescription drug importation is the purchase of prescription medications from outside of the U.S., often through overseas mail-order or online pharmacies. The FDA does not monitor prescription drugs that enter the drug supply chain from outside of the U.S., and cannot prevent harm to patients who engage in this practice.

While the price of drugs from other countries varies and is often cheaper than purchasing in the U.S., there is no guarantee of safety or efficacy of those medicines which can bring serious risk of harm to patients. Risks can include prescription drugs manufactured with inferior ingredients, improper handling or storage of medicines, or outright counterfeit copies sold to patients. Also, the practice of prescription drug importation is illegal.

Patients need to understand there is no certainty in knowing the true drug ingredients when they engage in prescription drug importation. And further, under circumstances where there is patient harm from improperly handled or counterfeit drugs, there is no judicial authority that can intervene on the patient's behalf.

While the federal FDA has authority over the safety and efficacy of prescription drugs in the U.S., it is critical to keep safety and risk of imported prescription medications front of mind when communicating with consumers.

POLICY RECOMMENDATION: Advocate for federal reform to the FDA, to include streamlining approval and safety processes for new drugs.

Increasing Access to Breakthrough Prescription Innovations

The Partnership for Prescription Assistance (PPA) is a comprehensive source of public and private programs that offer financial assistance to patients. Through their interactive website, low-income and uninsured individuals can apply to be connected to free health clinics or to a program that will help them obtain the prescription medicines they need.

Through the PPA, over 10 million Americans have gained access to prescription medicines through 475 public and private programs and 200 biopharmaceutical companies that provide access to over 2,500 prescription medications. Once the application and approval process for each patient has been facilitated, pharmaceutical companies coordinate with the patient's physician to assist the patient in obtaining their prescription medicine.

Find out more at www.pparx.org.

Conclusion

The U.S. biopharmaceutical industry is a global leader in investment in R&D and leads the discovery of pioneering medicines that improve quality of life and provide life-saving treatments. As more prescription innovations come to market, healthcare delivery in the U.S. will shift from treating disease and chronic conditions, to managing and preventing disease and chronic conditions.

Policies that limit or set the price for what patients and providers will pay for prescription drugs will lead to less investment in R&D for new life-saving drugs over time. For elected officials, the best option to balance patient access and affordability is to implement outcome-based payment models for brand and specialty drugs, while also discouraging exorbitant patient cost-sharing in health insurance deductibles and co-pays. Through these initiatives we can continue to foster a regulatory environment that will preserve our role as global innovators in medical advancement.

ABOUT CENTER FOR INNOVATION & TECHNOLOGY

The ALEC Center for Innovation and Technology provides state lawmakers with guides, data, research and a structure to imagine and create a plan of action for how innovation could benefit their states. Whether improving processes, creating products or developing new ideas, the Center provides a place for breakout inspiration and examination of policy improvements.

States have the opportunity to address policy challenges through innovation and experimentation and to lead by being the "laboratories of democracy." Most of the challenges are not easy, but innovation is often the way through, and states are best equipped for this challenge. Confronting challenges in these "laboratories" and taking the risks to create a better tomorrow provides a best practices blueprint for other states and the federal government. States are the incubators of solutions. But even when the creative goes astray, the experience provides valuable insight for other states as they grapple with their challenges.

"Solving real problems with relevant solutions is the key to any successful public policy agenda. In other words, innovation is just as much about identifying the problem as it is about creating the solution. To that end, the Center for Innovation and Technology considers current and potential state policy seeking breakout solutions," says Bartlett Cleland, head of the Center for Innovation and Technology. "The Center is the resource to assist state lawmakers in positioning their state to be an innovation leader today and for the future."

The secrets of America's success at invention are flexibility, the willingness to experiment and learn from mistakes, an inherent love of risk taking, adventure, discovery, entrepreneurship, the internal drive that gives permission to imagine and invent, the freedom to succeed and the freedom to fail… and a sensible government that stays out of the way of the magic. This is innovation.

ABOUT THE AUTHOR

Mia Palmieri Heck joined ALEC in August 2015. As the Health and Human Services (HHS) Task Force Director, Mia leads the nationwide effort to promote free-market, pro-patient healthcare reforms at the state level. In her immediate past position she served as an executive at a Texas-based child and family services provider, where she led the strategic planning and program development efforts for the agency.

From serving at the U.S. Department of Health and Human Services in the Administration of George W. Bush, to her work contributing to the design of community based models of care for at-risk populations, Mia's experience shows her early and lifetime commitment to advancing free-market principles in the spheres of health and human services.

A proud Texan, Mia holds a Bachelor of Arts in Government from the University of Texas at Austin; she then later earned a Healthcare MBA from George Washington University in Washington, D.C.

i. American Cancer Society Cancer Facts and Figures 2016, Accessed August 2016 http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2016/index

ii. The Telegraph, 'Patients 'waiting up to nine years' for NICE to approve drugs' May 16, 2012 http://www.telegraph.co.uk/news/health/news/9268737/Patients-waiting-up-to-nine-years-for-NICE-to-approve-drugs.html

iii. IMS Institute for Healthcare Informatics, "Medicines Use and Spending in the U.S. A Review of 2015 and Outlook to 2020" Published April 2016

iv. Centers for Disease Control and Prevention National Health Expenditure, Selected Years 1960 – 2014, Table 94 http://www.cdc.gov/nchs/data/hus/hus15.pdf#093

v. IMS Institute for Healthcare Informatics, Medicines Use and Spending in the U.S., April 2016 https://morningconsult.com/wp-content/uploads/2016/04/IMS-Institute-US-Drug-Spending-2015.pdf

vi. PwC Medical Cost Trend: Behind the Numbers 2017, June 2016 http://www.pwc.com/us/en/health-industries/health-research-institute/behind-the-numbers.html

vii. Drug Channels Website: What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing By Adam J. Fein, Ph.D. Thursday February 5, 2015 http://www.drugchannels.net/2015/02/what-gileads-big-hepatitis-c-discounts.html#more

viii. Fitch, Iwasaki, Pyenson, Engel, "Health care Reform and Hepatitis C: A Convergence of Risk and Opportunity," Milliman December 2013 http://us.milliman.com/uploadedFiles/insight/2013/convergence-of-risk-and-opportunity.pdf

ix. The Pharmaceutical Care Management Association (PCMA) website, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, Accessed October, 2016. http://www.pcmanet.org/research/pharmacy-benefit-managers-pbms-generating-savings-for-plan-sponsors-and-consumers

x. Visante, Pharmacy Benefit Managers (PBMs): Generating Savings for Plan Sponsors and Consumers, January 2016 http://www.pcmanet.org/research/pharmacy-benefit-managers-pbms-generating-savings-for-plan-sponsors-and-consumers

xi. Sun Sentinen Newspaper, State tells insurers to limit co-pays for HIV/AIDS drugs By Ron Hurtibise July 1, 2015 http://www.sun-sentinel.com/business/consumer/fl-hiv-drug-review-20150630-story.html

xii. Kaiser Health News, New Federal Standards For Marketplace Plans May Reduce Out-Of-Pocket Spending, By Michelle Andrews, January 22, 2016 http://khn.org/news/new-federal-standards-for-marketplace-plans-may-reduce-out-of-pocket-spending/

xiii. PhRMA analysis based on US Department of Health and Human Services, Agency for Healthcare Research and Quality, Medical Expenditure Panel Survey, 2013. Accessed April 2016 https://meps.ahrq.gov/mepsweb/data_stats/MEPSnetHC/startup

xiv. Kaestner R. Long C, Alexander C. National Bureau of Economic Research: Effects of prescription drug insurance on hospitalization and mortality, evidence from Medicare Part D, February 2014 http://www.nber.org/papers/w19948

xv. Manhattan Institute Alexander Tabarrok, Christopher-Paul Milne, Joseph A. DiMasi, An FDA Report Card: Wide Variance in Performance Found Among Agency's Drug Review, April 23, 2014 http://www.manhattan-institute.org/html/fda-report-card-wide-variance-performance-found-among-agencys-drug-review-6015.html#.VgGkRWRVhHw

xvi. IMS Institute for Healthcare Informatics, Avoidable costs in U.S. healthcare: the $200 billion opportunity from using medicines more responsibly, June 2013, Accessed July 2016 http://www.imshealth.com/en/thought-leadership/ims-institute/reports/avoidable-costs

xvii. The Menges Group, Medicaid Pharmacy Costs 2013 – 2014, Calculations from CMS, NHE Data, https://www.themengesgroup.com/presentation/menges_group_5_slide_series_march_2015_--_medicaid_pharmacy_rebates.pdf

xviii. The Menges Group Medicaid Pharmacy Costs FFY2013 & FFY2014 https://www.themengesgroup.com/presentation/menges_group_5_slide_series_march_2015_--_medicaid_pharmacy_rebates.pdf

xix. Centers for Disease Control and Prevention National Health Expenditure, Selected Years 1960 – 2014, Table 94 http://www.cdc.gov/nchs/data/hus/hus15.pdf#093

xx. The Telegraph, 'Patients 'waiting up to nine years' for NICE to approve drugs' May 16, 2012 http://www.telegraph.co.uk/news/health/news/9268737/Patients-waiting-up-to-nine-years-for-NICE-to-approve-drugs.html

xxi. Express Scripts, The $4 billion return on a promise kept, By Steve Miller, MD January 27, 2015 http://lab.express-scripts.com/lab/insights/specialty-medications/the-4-billion-return-on-a-promise-kept

xxii. IMS Institute for Healthcare Informatics, Global Outlook for Medicines through 2018, Accessed July 2016 http://www.imshealth.com/en/thought-leadership/ims-institute/reports/global-outlook-for-medicines-through-2018#ims-form

xxiii. Tufts Center for the Study of Drug Development Impact Report Volume 17 No. 3 May/June 2015.


ALEC
American
Legislative
Exchange
Council
LIMITED GOVERNMENT • FREE MARKETS • FEDERALISM