

Getting to the Root of High Prescription Drug Prices

Henry Waxman
Chairman
Waxman Strategies

Bill Corr
Senior Advisor
Waxman Strategies

Kristi Martin
Vice President
Waxman Strategies

Sophia Duong
Director
Waxman Strategies

ABSTRACT

ISSUE: Historic increases in prescription drug prices and spending are contributing to unsustainable health care costs in the United States. There is widespread public support for elected officials to address the problem.

GOAL: To document the drivers of high U.S. prescription drug prices and offer a broad range of feasible policy actions.

METHODS: Interviews with experts and organizations engaged with prescription drug development and utilization, pricing, regulation, and clinical practice. Review of policy documents, proposals, and position statements from a variety of stakeholders.

FINDINGS AND CONCLUSIONS: Congress and regulators can undertake a wide range of policy actions to begin to rebalance incentives for innovation and price competition, prioritize patient access and affordability, and maximize the availability of information to patients, providers, and payers.

This issue brief was adapted from the Commonwealth Fund report, *Getting to the Root of High Prescription Drug Prices: Drivers and Potential Solutions*.¹ The report identifies the problems and drivers of high prescription drug prices as well as the many actions that can be taken to address them. The authors believe that by coming to agreement on the problems that need to be addressed, policymakers and stakeholders can find a path to bipartisan solutions.



BACKGROUND

Historic increases in prescription drug prices and spending are contributing to unsustainable health care costs in the United States. While rising prescription drug utilization is clearly a product of population growth, an aging population, and greater use of drugs in health care among all age groups, about one-third of the rise in prescription spending from 2010 to 2014 was a result of either price increases for drugs or a shift in prescribing toward higher-price products. Caught in the middle are patients. Faced with rising drug costs, too many must choose between taking life-saving drugs or paying the rent. And many Americans are concerned about how they will afford their medications in the future.

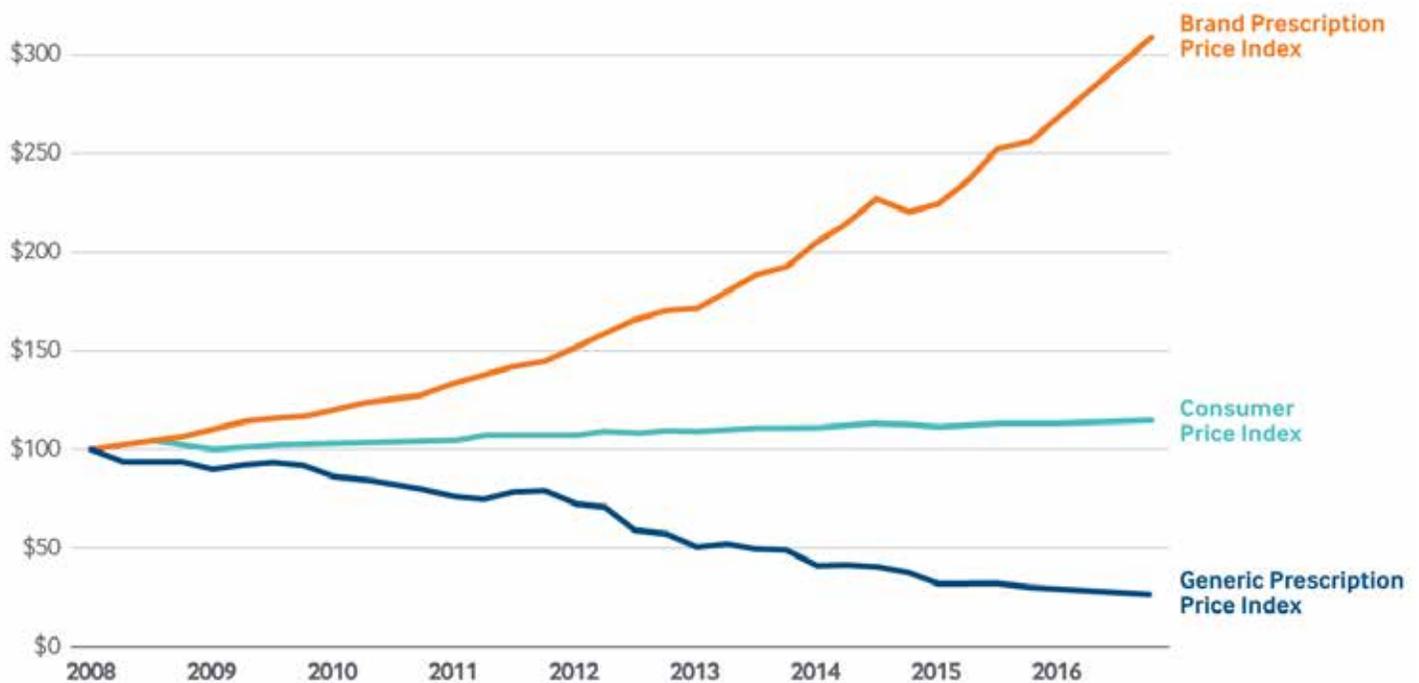
Because the pharmaceutical market is complex and diverse, it will be challenging to address high prices while still encouraging drug innovation, but it is certainly possible. Practical policies exist that could significantly curtail prices while incentivizing robust research and development.

This issue brief summarizes the major problems behind high U.S. prescription drug prices. These problems, along with their specific drivers, are creating barriers to health care access that affect patients, providers, and payers. We also offer some examples of feasible policy actions that illustrate how legislators and regulators can positively affect drug pricing both directly and indirectly.

GUIDING POLICY GOALS

U.S. prescription drug pricing over the past decade reflects a distortion of the policies that Congress has enacted to balance innovation and price competition and enable access to affordable medicine. Guided by the principles outlined below, policymakers can establish a more rational drug pricing system that meets the needs of all stakeholders: patients and consumers, public and private health care purchasers, health care providers, and the pharmaceutical industry.

Prices for Brand-Name Prescription Drugs Doubled Between 2008 and 2016



Source: Kaiser Family Foundation analysis of data from Express Scripts 2015 Prescription Price Index.

Rebalance Incentives for Innovation and Price

Competition: Pharmaceutical markets are most efficient when appropriate incentives for innovation are balanced with vigorous price competition. Markets also work best when information is available to all parties involved: manufacturers, patients, providers, and payers. While discovery and development of innovative therapies is a cornerstone of the U.S. health care system, it should not come at a price that leaves patients without access.

Prioritize Patient Access and Affordability: Drugs should be accessible and affordable to patients when they need them. Given the increasing role of pharmaceutical products in health care, their prices must be reasonable and sustainable for patients, government programs, and taxpayers.

Maximize the Availability of Information: Having information on the clinical value, comparative effectiveness, and pricing of prescription drugs would facilitate patient-centered decision-making—enabling patients to work with their clinician in choosing drug therapies that best fit their needs, preferences, and circumstances. Drug manufacturers should be able to clearly articulate and justify their drug pricing decisions in a clear, straightforward manner to the public.

THE DRIVERS OF HIGH DRUG PRICES AND SELECTED EXAMPLES OF POLICY ACTIONS THAT CAN HELP

(See the full report for complete list of feasible policy actions.)

Problem: High prices and high annual increases for patented brand-name drugs and “orphan drugs” create barriers to access.

New brand-name drugs are granted patent and market-exclusivity protections to give drug manufacturers time to recoup the costs of developing new treatments and cures and to enable them to achieve a return on investment. During this period of market protection, manufacturers have total discretion to set introductory and annual prices, and there is only limited competition on price—primarily from clinically comparable brand-name drugs (also

known as comparator drugs). In 2014, 33 new brand-name drugs were launched in the U.S., and only eight had a direct price competitor at the time they were introduced.²

Over the past decade, introductory prices for new brand-name drugs have reached unprecedented levels. One study found that oral anticancer drugs introduced in 2014 were six times more expensive at launch, when adjusted for inflation, than drugs introduced in 2010.³ Once new drugs are introduced, many manufacturers use patent protection and market-exclusivity protections to significantly raise prices each year, even when there have been no significant improvements made. Between 2014 and 2015, retail prices for 268 brand-name prescription drugs widely used by older Americans increased by an average of 15.5 percent, 130 times the rate of general inflation.⁴ Price increases for specialty pharmaceuticals used to treat complex conditions are often even greater.⁵

Some manufacturers develop their new drugs by leveraging federally funded research and discoveries. In fact, nearly half of basic research is funded through federal government investments, with roughly 75 percent of new innovative drugs supported by federal funding.^{6,7} There are concerns that the economies of developing drugs with government grants are not being passed on to consumers and payers.

Possible Solutions:

- Alter patent protections and market exclusivities to introduce price competition earlier. Alternatively, explore solutions that tie the period of market exclusivity to the manufacturer’s return on investment in research and development.
- Establish alternative government-purchasing projects for drugs that protect public health, such as medicines that prevent and limit the spread of serious infections.
- Require additional information from manufacturers seeking orphan drug status. This may include information on whether the manufacturer plans to pursue additional orphan drug indications and information on drug utilization, if the drug has already been approved by FDA for orphan or non-orphan indications.⁸

Problem: Some manufacturers create, or take advantage of, natural monopolies for drugs that enable them to sharply increase prices.

There are 182 drugs that no longer have patent protection or any associated generics available.⁹ These natural monopolies create the opportunity for manufacturers to maintain patent-era pricing or even engage in price gouging.

A drug company can also obtain a natural monopoly with an older drug when other companies producing the same drug withdraw from the market for commercial reasons, manufacturing difficulties, or safety reasons. Alternatively, competition may dry up when a manufacturer merges with or acquires other companies that made a drug.

Possible Solutions:

- Provide targeted incentives that the U.S. Food and Drug Administration (FDA) can implement to generate competition, such as the use of voucher programs or expedited-review pathways.
- Ensure proactive government monitoring and oversight of competition in pharmaceutical markets.

Problem: Lack of robust competition among manufacturers of generic drugs, biologics, and biosimilars results in less price competition and higher prices.

More than 500 drugs have only one marketed generic.¹⁰ In some cases, the market for a drug is simply too small. Some brand-name manufacturers, meanwhile, block potential competitors from obtaining drug samples needed to conduct bioequivalence studies, a key step in developing a generic.

Other factors restricting competition include:

- the rising trend of mergers and acquisitions among manufacturers, which has led to more concentrated, less-competitive markets¹¹
- drug shortages, including those caused by supply disruptions
- the temporary or permanent removal of a generic from the market, whether resulting from a temporary need to address drug-safety or manufacturing issues or from low profits.

Lack of competition in the expanding biologic drug sector is another major concern. Biologics, which are typically

derived from human or animal proteins, are more complex than small-molecule drugs synthesized from chemical compounds. Because of their complexity, they do not have strictly generic alternatives—although there are equivalents, known as biosimilars. In 2016, \$105.5 billion was spent on biologics, with some drugs costing \$250,000 annually per patient.

The lack of a fully developed regulatory framework has greatly limited the introduction of biosimilars.^{12,13,14,15} While passage of the Biologics Price Competition and Innovation Act in 2010, part of the Affordable Care Act, set a landmark precedent by creating a pathway for biosimilar entry, the FDA is still in the developing stages of building and implementing this pathway for approval. In the meantime, the U.S. lags the rest of the world in bringing biosimilars to market.

Possible Solutions:

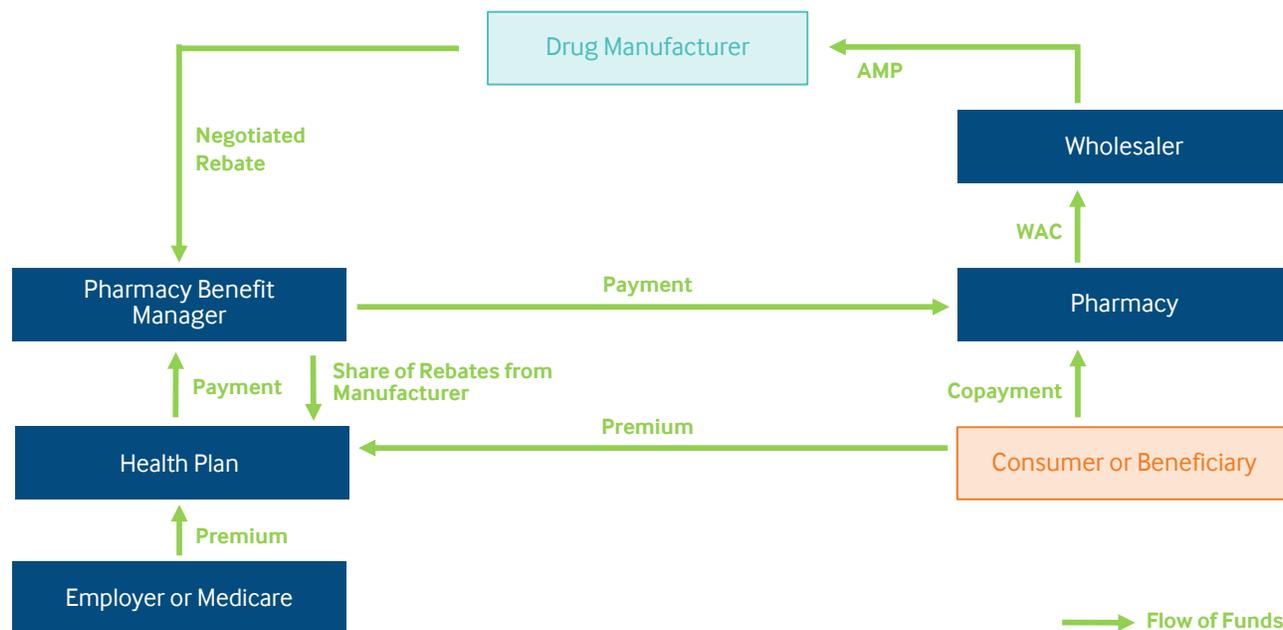
- Enable the FDA to provide generic manufacturers with targeted incentives to generate competition, such as awards for entering a sole-source market or developing products to relieve drug shortages, or priority or expedited review for manufacturers that are second and third entrants into generic markets.
- Eliminate provisions of the Hatch-Waxman Act that delay the introduction of generics, including the 30-month delay in generic approval (when a brand-name manufacturer claims patent infringement) and the 180-day exclusivity period for the first generic approved.¹⁶
- Require the FDA to finalize guidance to spur competition in the biologics market, including guidance on labeling and interchangeability.

Problem: Some manufacturers engage in anticompetitive behaviors and take advantage of current patent protection policies to undermine competition.

States and federal officials are investigating multiple generic drug companies for artificially inflating prices for diabetes and antibiotic drugs.¹⁷ Executives from one company face federal charges for price fixing, rigging bids, and allocating customers for certain generic versions of the antibiotic doxycycline.¹⁸ A 500-pill bottle of doxycycline increased from \$20 to \$1,849 over six months.

The Flow of Payment for Brand-Name Drugs Is Complex

Excludes federally mandated rebate programs



Note: AMP = Average Manufacturer Price, WAC = Wholesale Acquisition Cost.

Source: Congressional Budget Office.

Similarly, three brand-name manufacturers are facing accusations of price-fixing insulin products in response to apparent matching price increases. Over the past decade, the price of insulin has tripled.¹⁹

Some brand-name manufacturers enter agreements with other manufacturers to suppress competition. These include pay-for-delay, or reverse-payment, settlements, where a brand-name drug manufacturer pays a patent challenger to keep a generic competitor off the market until an agreed-on date. This date usually corresponds to the 180-day market-exclusivity period for first generics, or the agreement takes advantage of the 30-month approval delay. The Federal Trade Commission asserts that pay-for-delay deals are anticompetitive and cost Americans about \$3.5 billion annually in higher health care costs.²⁰

Another tactic, “product hopping,” involves creating a “new” product that is similar to the original product. With a goal of obstructing generic manufacturers, the

brand-name manufacturer makes modest reformulations that offer little or no therapeutic advantages and then withdraws the original product from the market, forcing consumers to switch to the reformulated drug.

Other manufacturers develop a dense portfolio of patents to cover a single drug—often referred to as a patent cluster or thicket—to protect their product and eliminate competition.²¹

Possible Solutions:

- Clarify federal law to prohibit pay-for-delay and product-hopping.
- Establish policies to require patent applicants to demonstrate significant differences, originality, or additional benefit for secondary patents; strengthen the patent review system to ensure that competitors opposing the patent can play a productive role; and extend the window for challenging a patent’s validity.

Problem: The pharmaceutical distribution system does not make essential pricing information available to patients, providers, and payers at the point of care, making it difficult for patients to make the best decisions about their care.

The major players in the drug distribution system include manufacturers, wholesalers, pharmacy benefit managers (PBMs), retailers, and insurers.²² The number of intermediaries in the system creates a complex flow of payments and rebates.

A lack of transparency in the amount of rebates and payments each entity charges or receives makes it difficult to determine if entities are inappropriately driving up drug prices. No regulations or requirements exist for these entities to disclose information on prices or rebates to each other or the public. Moreover, patients, providers, and payers lack information about the comparative effectiveness of drugs at the time when critical health care decisions are made.

Possible Solutions:

- Require transparency in drug pricing and in price increases. For example, the federal government could require manufacturers and PBMs to report information on rebates and prices paid.
- Eliminate manufacturers' practices that obscure pricing, such as providing coupons to consumers in commercial settings.
- Invest in comparative-effectiveness research.

Problem: Federal law imposes limitations on state authority to negotiate prices for Medicaid and implement other measures to reduce high drug costs.

While there is some flexibility with respect to Medicaid drug coverage, federal law limits the authority of states

to exclude a drug from coverage or deploy value-based purchasing.

Currently, state Medicaid programs may enter into purchasing pools to allow them to negotiate prices jointly. There are also efforts in some states to involve other agencies or populations, along with Medicaid. A state could act as negotiator and purchaser on behalf of all its coverage programs, thus increasing its negotiation and purchasing power.

Possible Solution:

- Enable states to operate PBMs to broaden their purchasing and negotiating power, by including Medicaid, along with all other state coverage programs, in their negotiations as purchasers.

CONCLUSION

There is widespread public support for addressing the problem of high prescription drug prices. Any effort must start with identifying common ground on the factors that drive high drug prices. Ideally, policymakers would be guided by the goals of rebalancing incentives for innovation and price competition, prioritizing patient access and affordability, and maximizing the availability of information to improve patient care.

It also will be important to recognize how Congress was able to tackle similarly complicated prescription drug issues in the 1980s, when lawmakers pursued and passed bipartisan legislation balancing the right incentives for innovation with price competition. Congress should take a page out of this earlier playbook, which succeeded in creating a generic drug market and incentives for finding new treatments and breakthrough cures.

NOTES

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- ³ S. B. Dusetzina, “Drug Pricing Trends for Orally Administered Anti-Cancer Medications Reimbursed by Commercial Health Plans, 2000–2014,” *JAMA Oncology*, July 2016 2(7):960–61.
- ⁴ S. W. Schondelmeyer and L. Purvis, *Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015* (AARP Public Policy Institute, Dec. 2016).
- ⁵ For example, first-generation disease-modifying treatments for multiple sclerosis, originally costing \$8,000 to \$11,000, now cost about \$60,000 per year. D. M. Hartung, D. N. Bourdette, S. M. Ahmed et al., “The Cost of Multiple Sclerosis Drugs in the U.S. and the Pharmaceutical Industry: Too Big to Fail?” *Neurology*, May 26, 2015 84(21):2185–92.
- ⁶ J. Mervis, “Data Check: U.S. Government Share of Basic Research Funding Falls Below 50%,” *Science Magazine*, published online March 9, 2017.
- ⁷ M. Mazzucato, “Op-Ed: How Taxpayers Prop Up Big Pharma, and How to Cap That,” *Los Angeles Times*, Oct. 27, 2015.
- ⁸ An orphan drug is a medicine or biological product developed for a rare disease or condition.
- ⁹ J. Woodcock, Testimony of Janet Woodcock, M.D., Before the U.S. House of Representatives, Committee on Energy and Commerce, Subcommittee on Health, *Generic Drug User Fee Act Reauthorization (GDUFA II) and Biosimilar User Fee Act Reauthorization (BsUFA II)*, Hearing on “Examining FDA’s Generic Drug and Biosimilar User Fee Programs,” March 2, 2017.
- ¹⁰ Question to Dr. Janet Woodcock, U.S. House of Representatives, Energy and Commerce Committee, Subcommittee on Health, Hearing on “Examining FDA’s Generic Drug and Biosimilar User Fee Programs,” March 2, 2017.
- ¹¹ For instance, Valeant Pharmaceuticals’ acquisition strategy acquired 100 companies, and part of this strategy was to increase prices as the market was consolidated. See S. M. Collins and C. McCaskill, *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System* (U.S. Senate, Special Committee on Aging, Dec. 2016).
- ¹² A. Brill, *Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry* (Matrix Global Advisors, July 2014).
- ¹³ A. S. Kesselheim, J. Avorn, and A. Sarpatwari, “The High Cost of Prescription Drugs in the United States: Origins and Prospects for Reform,” *Journal of the American Medical Association*, Aug. 23/30, 2016, 316(8):858–71.
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- ¹⁵ IMS Institute for Healthcare Informatics, *Medicines Use and Spending in the U.S.: A Review of 2016 and Outlook to 2021* (IMS Health, May 2017).
- ¹⁶ The Drug Price Competition and Patent Term Restoration Act—commonly referred to as Hatch-Waxman—extended patent terms and introduced market-exclusivity protections for certain types of drugs. The law also provides for a generic drug approval system that ensures safe, therapeutically equivalent generic drugs are available at lower prices when patents and other market exclusivities expire.
- ¹⁷ K. Thomas, “20 States Accuse Generic Drug Companies of Price Fixing,” *New York Times*, Dec. 15, 2016.

- ¹⁸ U.S. Department of Justice, “[Former Top Generic Pharmaceutical Executives Charged with Price-Fixing, Bid-Rigging and Customer Allocation Conspiracies](#),” News release (DOJ), Dec. 14, 2016).
- ¹⁹ K. Thomas, “[Drug Makers Accused of Fixing Prices on Insulin](#),” *New York Times*, Jan. 30, 2017.
- ²⁰ Federal Trade Commission, *Pay-for-Delay: When Drug Companies Agree Not to Compete* (FTC, n.d.).
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- ²² A. J. Fein, “[Follow the Dollar: The U.S. Pharmacy Distribution and Reimbursement System](#),” *Drug Channels*, published online Feb. 3, 2016.

ABOUT THE AUTHORS

Rep. Henry Waxman is one of the most effective legislators of the last 40 years, with health care among his central concerns. During his time in Congress, Waxman used legislative tools to unmask the tobacco industry after years of deception and authored the Affordable Care Act, which has helped 20 million more Americans get health insurance. The Hatch-Waxman Act helped create the generic drug industry, while the Orphan Drug Act incentivized the growth of an industry that has given hope to the millions of Americans afflicted with rare diseases. Evident in all of Waxman's work is his commitment to concrete solutions that transform people's lives for the better. His tenacity has earned him widespread recognition from journalists, fellow elected officials, and President Obama, who described him as "one of the most accomplished legislators of this or any era."

Bill Corr has spent the bulk of his impressive career advocating for better health care access at almost every level of society. Most recently, he served as deputy secretary of the U.S. Department of Health and Human Services from 2009 to 2015. Corr returned to the department after serving as executive director of the Campaign for Tobacco-Free Kids, a privately funded organization established to focus the nation's attention and action on reducing tobacco use among both kids and adults. From March 1998 until 2000, Corr served as chief counsel and policy director for Senate Minority Leader Tom Daschle. Before working this, he served as the chief of staff for the Department of Health and Human Services. In that capacity, he was principal advisor to Secretary Donna E. Shalala on all major policy and management issues and initiatives. He also was deputy assistant secretary for health for the department and counselor to the secretary prior to becoming chief of staff. From 1989 until 1993, Corr served as chief counsel and staff director for the Subcommittee on Antitrust, Monopolies and Business Rights of the Senate Committee on the Judiciary under Chairman Howard M. Metzenbaum. Corr also served as counsel to the Subcommittee on Health and the Environment of the House of Representatives Committee on Energy and Commerce under Chairmen Paul Rogers and Henry A. Waxman.

Kristi Martin most recently was a senior advisor in the Office of Health Reform at the Department of Health and Human Services, where she had primary oversight responsibility for the coordinated and timely implementation of the public health and prevention policy portfolio of the Affordable Care Act. In addition, she provided support and coordination related to cross-cutting departmental initiatives, including the rising cost of drugs and women's health issues. Previously, Martin served as team lead for the State Analysis and Oversight Team in National Healthcare Operations at the U.S. Office of Personnel Management. In this role, she led policy development and state engagement efforts to implement the Multi-State Plan Program. Martin has also worked in the Center for Consumer Information and Insurance Oversight and Government Accountability Office and at American Cancer Society and Easter Seals.

Sophia Duong is experienced working with a diverse portfolio of organizations, ranging from nonprofits, trade associations, and multinational corporations. Prior to joining Waxman Strategies, Duong was a senior associate at Avalere Health, where she worked with an array of clients, providing insight and analysis on health policy issues. In particular, she was a Medicaid subject-matter expert, assisting clients in understanding how changes within the program could affect their business opportunities. Previously, Duong was a state health policy analyst at the Georgetown University Center for Children and Families. In this role, Sophia provided technical assistance, policy analysis, strategic planning, and communications advice to state based advocacy organizations across the country.

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For more information about this brief, please contact:

Henry Waxman

Chairman, Waxman Strategies

henry@waxmanstrategies.com

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