



**The Pharmaceutical Supply Chain and Prescription Drug Costs:  
“The Problem is the Price”**

**by**

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**for the  
House Energy and Commerce Committee  
Subcommittee on Health**

**December 13, 2017**

## Introduction

Chairman Burgess, Ranking Member Green and members of the subcommittee, I am Matt Eyles, Senior Executive Vice President and Chief Operating Officer of America's Health Insurance Plans (AHIP). AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of families, businesses, communities and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access and well-being for the American people.

We appreciate this opportunity to testify on issues surrounding the pharmaceutical supply chain and solutions that are needed to help millions of Americans who are burdened by out-of-control prescription drug prices. AHIP's members negotiate with health care providers and pharmaceutical manufacturers on behalf of consumers and other health care purchasers (e.g., employers, government) to provide coverage for high-quality treatments and services at the most competitive prices possible. Health insurance providers offer comprehensive coverage under the pharmacy benefit for prescription drugs delivered through retail, mail order, and specialty pharmacies. Health plans also provide coverage under the medical benefit for physician-administered drugs, biologics, and devices in outpatient and inpatient settings. This gives health plans a unique perspective into the pharmaceutical supply chain and a 360-degree view of the broader U.S. health care system – working with pharmacy benefit managers and negotiating with drug and device manufacturers, pharmacies, physicians, and hospitals to ensure that enrollees have coverage for the treatments and services they need.

As the committee explores the role of various participants in the supply chain, we urge you to recognize that the entire pricing process is driven entirely by the original list price of a branded drug – which is determined solely by the drug company, not by the market or any other participant in the pharmaceutical supply chain. Congress needs to address this reality – **that the problem is the price** – as part of any strategy for reducing pharmaceutical costs for the American people.

Out-of-control prescription drug prices are a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power that exist nowhere else in the U.S.

economy. The end result is that everyone pays more – from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

Bold steps are needed, at both the legislative and regulatory levels, to ensure that people have access to affordable medications. With the right solutions that increase competition, choice, and patient control, we can deliver affordable prescription drugs – while at the same time protecting and supporting innovations to deliver new treatments and cures for patients.

Our statement focuses on the following topics:

- The consequences that out-of-control prescription drug prices have on consumers;
- How health plans work hard on behalf of all consumers to negotiate lower prescription drug costs, while prescription drug manufacturers set sky-high list prices that serve as the starting point for rebate negotiations and the overall pricing process; and
- Our recommendations for reducing prescription drug prices through market-based solutions that deliver real competition, create more consumer choice, and ensure that open and honest drug pricing is tied to the value delivered to patients.

### **The Impact of Out-of-Control Prescription Drug Prices**

Rising prescription drug prices and costs impose a heavy burden on all Americans. From patients who cannot afford life-saving medications, to consumers who pay higher and higher premiums because of higher and higher drug prices, to employers who must divert dollars that could be used for salaries to pay for more expensive health services, to hardworking taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound.

It is important to understand the unambiguous root causes of this problem: lack of real market competition due to the extension and distortion of government-granted exclusivity and patent protections, opaque pharmaceutical pricing practices, questionable sales and marketing practices, and limited correlation between drug prices and the value they deliver to patients.

Even for products that have been on the market for decades, sharp price increases are not uncommon. For example, one study shows that the price of insulin has increased more than 240 percent over the past decade – from \$88.20 per vial in 2007 to \$307.20 per vial today – despite

the fact that insulin has been widely available for the last 90 years. With no generic competition in the U.S., diabetes patients are limited to brand-name versions costing hundreds of dollars per vial.<sup>1,2</sup>

EpiPens offer another good example. The unjustified price increases for EpiPens generated well deserved scrutiny last year. From 2008 to 2016, the list price of an EpiPen 2-Pak rose an astonishing 500 percent – with zero improvements to the quality of the medication. Because of this out-of-control price spike, the cost of co-insurance to cover the medication increased by 477 percent (\$127)<sup>3</sup>. The consequence for hardworking families is that they have less money in their pockets to buy gas, groceries, or save for college or retirement.

Spending on prescription drugs continues to grow at a rapid and unsustainable rate, driven in large part by both high launch prices for new therapies and treatments as well as price increases for existing brand-name drugs. In 2015, U.S. spending on prescription drugs totaled \$457 billion and represented 16.7 percent of total personal health care spending (includes retail prescription drugs and drugs provided in a hospital setting).<sup>4</sup> According to the Centers for Medicare & Medicaid Services (CMS), total prescription drug spending is projected to reach \$597.1 billion by 2025.<sup>5</sup>

According to the Milliman Medical Index, a widely used benchmark for estimating health care costs for a family of four with employer-sponsored health insurance coverage, prescription drug spending will increase by 8 percent in 2017, which is more than double the 3.6 percent increase in overall medical trend.<sup>6</sup> The report notes that “because prescription drug expenses have grown more quickly than other healthcare expenditures, drugs have increased from approximately 13% of the total MMI in 2001 to 17.1% in 2017.”<sup>7</sup> Similarly, Segal Consulting, a prominent benefits

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<sup>1</sup> Jeremy A. Green, M.D., Ph.D. and Kevin R. Riggs M.D., M.P.H. “Why Is There No Generic Insulin? Historical Origins of a Modern Problem.” *New England Journal of Medicine*; March 19, 2015.

<sup>2</sup> Several Probes Target Insulin Drug Pricing, Kaiser Health News, October 28, 2017

<https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141>

<sup>3</sup> Calculated by using EpiPen list prices from 2008 and 2016, assuming a 30% co-insurance rate off of PBM payment rate, and using CBO’s reported “typical” PBM payment rate of 85% of list price plus a \$2.00 dispensing fee (<https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>)

<sup>4</sup> HHS-ASPE Report—Observations on Trends in Prescription Drug Spending. March 8, 2016.

<https://aspe.hhs.gov/pdf-report/observations-trends-prescription-drug-spending>

<sup>5</sup> National Health Expenditure Projections, 2016-2025: Price Increases, Aging Push Sector to 20 Percent of Economy. Sean P. Keehan, et al. *Health Affairs*; March 2017.

<https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2016.1627>

<sup>6</sup> 2017 Milliman Medical Index. Chris Girod, Sue Hart, and Scott Weltz. May 2017.

<http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>

<sup>7</sup> 2017 Milliman Medical Index. Chris Girod, Sue Hart, and Scott Weltz. May 2017.

<http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>

consulting firm, estimates that prescription drug spending for employer-sponsored plans will increase by 10.3 percent in 2018 – with a 17.7 percent cost increase in specialty drugs and biologics.<sup>8</sup> Prescription drug spending trends are primarily driven by price inflation (8.8%) as opposed to increases in utilization (2.1%), according to the Segal Consulting study.<sup>9</sup>

The pharmaceutical cost crisis is clearly demonstrated by numerous research findings:

- **Out-of-Control Drug Prices and Costs Are a Major Component of Premiums:** A March 2017 AHIP analysis concluded that 22 cents of every dollar spent on health insurance premiums goes to pay for prescription drugs – outpacing the amount spent on physician services, inpatient hospital services, and outpatient hospital services.<sup>10</sup> These costs impose a heavy burden on consumers, employers, government programs, taxpayers, and the entire health care system. When prescription drug prices go up, the cost of health insurance goes up. That is a fundamental economic reality: rising health care costs, including drug costs, are driving increases in the cost of health coverage.
- **Financial Burden on Hospitals and Providers:** An October 2016 study commissioned by the American Hospital Association and the Federation of American Hospitals cautioned that hospitals “bear a heavy financial burden when the cost of drugs increases and must make tough choices about how to allocate scarce resources.” This study highlighted an example of one hospital for which the price increases of four common drugs (which ranged between 479 and 1,261 percent) cost the same amount in 2015 as the salaries of 55 full-time nurses.<sup>11</sup>
- **Unfair Burden of High Drug Prices for American Consumers, Businesses and Taxpayers:** In a March 2017 *Health Affairs* blog, researchers at the Memorial Sloan Kettering Center for Health Policy and Outcomes analyzed the 15 companies selling the top 20 drugs (by sales) in the United States. Researchers reported that: (1) list prices in other developed countries averaged just 41 percent of U.S. net drug prices; and (2) the additional

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<sup>8</sup> Segal Consulting--High Rx Cost Trends Projected to Be Lower for 2018. Fall 2017.

<sup>9</sup> Ibid.

<sup>10</sup> “Prescription Drugs Are Largest Single Expense of Consumer Premium Dollars,” AHIP, March 2, 2017. <https://www.ahip.org/health-care-dollar/>. This AHIP estimate understates the actual impact of prescription drugs on insurance premiums, as drugs administered in hospital inpatient settings were excluded.

<sup>11</sup> “Trends in Hospital Inpatient Drug Costs: Issues and Challenges,” NORC, October 11, 2016. <http://www.aha.org/content/16/aha-fah-rx-report.pdf>

income generated by higher U.S. net drug prices totaled \$116 billion in 2015.<sup>12</sup> The authors further stated: “We found that the premiums pharmaceutical companies earn from charging substantially higher prices for their medications in the US compared to other Western countries generates substantially more than the companies spend globally on their research and development. This finding counters the claim that the higher prices paid by US patients and taxpayers are necessary to fund research and development. Rather, there are billions of dollars left over even after worldwide research budgets are covered.”

- **Higher Prices Often Do Not Mean Better Outcomes:** While some recent high-priced, breakthrough medications have improved patient outcomes, this is not always the case. For example, an April 2015 study by researchers from the National Institutes of Health (NIH) in *JAMA Oncology* examined 51 oncology drugs approved by the Food and Drug Administration (FDA) from 2009 through 2013. Researchers concluded that current pricing models were irrational and had no connection to better patient outcomes. Remarkably, the NIH researchers found that prices had no significant correlation to improvements in progression-free survival or overall survival.<sup>13</sup> With new cancer drugs now often costing well over \$100,000 annually, manufacturers appear to be setting the price of new therapies based on the highest-priced oncology treatment approved most recently by the FDA rather than the value or the improved outcomes they deliver to patients.
- **“Unreasonable” Drug Prices Forcing Tradeoffs between Taking Medicines and Other Necessities:** A September 2016 tracking poll from the Kaiser Family Foundation found that 77 percent of Americans believe that prescription drug costs are “unreasonable.”<sup>14</sup> The difficulty in affording unreasonably priced prescription drugs can lead to treatment non-adherence, which can harm patient health creating adverse outcomes and leading to expensive complications. According to a survey by *Consumer Reports*, many respondents took “potentially dangerous” steps to limit the impact of high drug costs: not filling a prescription (17 percent), skipping a scheduled dose (14 percent), or taking an expired medication (14 percent). This survey also found that 19 percent of respondents spent less on

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<sup>12</sup> “R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices,” Nancy Yu, Zachary Helms, and Peter Bach, March 7, 2017. <http://healthaffairs.org/blog/2017/03/07/rd-costs-for-pharmaceutical-companies-do-not-explain-elevated-us-drug-prices/>

<sup>13</sup> “Five Years of Cancer Drug Approvals: Innovation, Efficacy, and Costs,” Sham Mailankody, MB BS; Vinay Prasad, MD, MPH, *JAMA Oncology*, July 2015. <http://oncology.jamanetwork.com/article.aspx?articleid=2212206>

<sup>14</sup> Kaiser Health Tracking Poll: September 2016. <http://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>

groceries, and 15 percent postponed paying other bills so they could afford their prescription drugs.<sup>15</sup>

These facts paint a clear picture of the crisis we face: drug companies exploit a broken market to set seemingly unbounded prices for seemingly unlimited periods while consumers, businesses, and taxpayers bear the staggering costs.

### **Understanding the Role of Health Plans in the Supply Chain: Negotiating Lower Costs for All Consumers**

Consumers are taking a more active role in their health decisions, including how to manage the rising prices and cost of prescription drugs, and health plans are providing better cost and quality comparison tools for individuals and families to make informed choices about their care.

According to an AHIP study published in the *American Journal of Managed Care (AJMC)*, 90 percent of plans with price estimator tools educated consumers on their potential out-of-pocket costs, such as co-pays, coinsurance, and deductibles that they might incur for specific procedures or services.<sup>16</sup> Research shows that the advance availability of price information can help consumers make health care decisions tailored to their specific care needs. Additionally, many of these resources are easily-accessible consumer tools available through mobile apps, including coverage information, provider directories listing the network of participating and/or preferred pharmacies. This information gives consumers more control over their care and more choices for their coverage.

Overall, when compared to the total spending for retail prescription drugs, consumer out-of-pocket spending – cash payments, deductibles, coinsurance, and copayments – have significantly decreased since the 1990s. Consumer out-of-pocket spending has declined from 57 percent of U.S. retail drug spending in 1990 to 14 percent in 2015, and spending by commercial and government payers rose from 43 percent to 86 percent of U.S. retail drug expenditures during this same period.<sup>17</sup> A 2016 Kaiser analysis found that after insurance coverage for individuals in

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<sup>15</sup> “Some Americans take risks with needed drugs due to high costs,” Consumer Reports, September 2014. <http://www.consumerreports.org/cro/2014/09/some-americans-take-risks-with-needed-drugs-due-to-high-costs/index.htm>

<sup>16</sup> “Characterizing Health Plan Price Estimator Tools: Findings From a National Survey,” Higgins A, Brainard N, Veselovskiy G., *AJMC*, February 2016.

<sup>17</sup> Centers for Medicare & Medicaid Services (CMS), “National Health Expenditures Projections 2016-2025,” and National Health Expenditure (NHE), “Historical and Projections 1960-2025,” at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsProjected.html> The NHE accounts detail how much

employer-sponsored coverage, the average out-of-pocket cost for a person who purchases prescription drugs is \$12 a month.<sup>18</sup>

Importantly, since 2014, nearly all consumers with minimum essential coverage have been protected by annual limits on maximum out-of-pocket (MOOP) costs. With the exception of certain grandfathered plans in effect before March 2010, all health plans in the individual and group markets (including large group and self-insured plans) have maximum out-of-pocket limits. This includes protecting patients against catastrophic exposure and financial ruin because of rising drug costs. These MOOP limits are reset and updated annually, providing the financial protection that patients deserve. While the federal limit for individual coverage is \$7,150 and \$14,300 for family coverage in 2017, many health plans have set their out-of-pocket limits far lower. The vast majority of individuals with employer-sponsored coverage (and those covered under Medicare Advantage prescription drug plans and Medicaid) have substantially lower limits.<sup>19</sup>

Prices for specialty-drug medications often significantly exceed a health plan's maximum out-of-pocket limits – protecting consumers from one of the highest and fastest growing prescription drug segments. An AHIP analysis of 150 drugs on specialty-drug formularies found that over half cost more than \$100,000 year – in other words, the *monthly cost* of many specialty drugs exceeds the annual MOOP.<sup>20</sup> While these drugs often provide tremendous clinical benefits when medically necessary, their high prices and growing use for treatment of chronic conditions in larger populations threatens the availability of affordable coverage options for *all consumers*. With an expected 225 new specialty drugs coming to market over the next five years, health plans, employers, and other stakeholders are searching for innovative, market-based strategies to restrain cost growth while simultaneously maintaining access to safe and effective drugs for patients.

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consumers pay each year to fill retail prescriptions including cash purchases, insurance deductibles, co-payments, and coinsurance. Annual insurance premiums are not included in out-of-pocket spending.

<sup>18</sup> The Henry J. Kaiser Family Foundation. “New Analysis Finds Out-of-Pocket Prescription Drug Spending Decreasing on Average, But More People Spending in Excess of \$1,000 a Year.” October 2016.

<sup>19</sup> “Employer Health Benefits 2016 Annual Survey” (exhibit 7.36), Kaiser Family Foundation and Health Research and Educational Trust, 2016. <http://files.kff.org/attachment/Report-Employer-Health-Benefits-2016-Annual-Survey>

<sup>20</sup> “High Priced Drugs: Estimates for Annual Per-Patient Expenditures for 150 Specialty Medications,” AHIP, April 2016.



## Reducing Prescription Drug Costs Through Rebate Negotiations

While prescription drug pricing in the private sector is complex, in many cases, health plans are able to negotiate with manufacturers to provide savings for all consumers. Health plans negotiate with drug manufacturers for lower prices – and then pass those savings on in the form of lower premiums and lower out-of-pocket costs for all consumers. The focus on how some of these savings, which sometimes take the form of “rebates,” are distributed to consumers – whether to a small group of patients or across the broader covered population – is a deliberate tactic to obscure the more serious issues surrounding the lack of competition, transparency, and accountability in the pricing of prescription drugs.

In discussing rebates, it is important to understand the role they play within the broader system for setting the cost of drugs that consumers pay at the pharmacy. It is also important to understand that for some branded drugs and biologics without therapeutic alternatives, manufacturers’ willingness to negotiate on price is small or nonexistent. Further, rebates are not commonly found for physician-administered drugs, which account for 30 percent of prescription drug spending.<sup>21</sup>

The bottom line is that the original list price of a drug is solely determined and controlled by the drug company – not the market – and it drives the entire pricing process. And if the original list price is high, the final cost that a consumer pays will be high. **It is that simple: the problem is the price.**

Unfortunately, manufacturers of branded drugs and biologics are working to divert attention from high prescription drug prices and instead point to problems in the drug supply chain and the role of wholesalers and pharmacy benefit managers (PBMs). However, we should focus on how the supply chain actually works. Manufacturers sometimes sell their products directly to the pharmacy (e.g., large chain retail pharmacies), but more often sell their products through a wholesaler. The price that pharmacies and wholesalers pay is highly correlated to the original list price set by the manufacturer. Wholesalers and some pharmacies may acquire the drug at a modest reduction off the list price as a result of volume and/or prompt pay discounts. These discounts are not significant because wholesalers do not influence the “market share” of specific prescription drugs. Wholesalers then take possession of the drug and distribute and resell the

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<sup>21</sup> “Trends in Specialty Drug Benefits,” Pharmacy Benefit Management Institute, 2017.

drug to pharmacies (e.g., smaller community pharmacies) after a small markup above the discounted price.<sup>22</sup> This total cost represents the pharmacy's acquisition cost.

At this point, the consumer enters the process. For individuals who lack health insurance but are prescribed a medication, they often pay the highest prices, especially for branded drugs. Typically, they pay the full list price set by the drug company (or the pharmacy acquisition cost) plus a markup.

By contrast, for individuals with insurance who are dispensed a prescription drug from a pharmacy in the health plan's network, the pharmacy typically communicates electronically with a PBM, which administers drug benefits under a contract with the health plan. From the PBM, the pharmacy receives confirmation of coverage; whether the drug is subject to any utilization management tools, such as prior authorization; whether there are any potential safety issues, such as quantity limits or drug-drug interactions; the reimbursement amount to be paid by the plan; and the co-payment or co-insurance owed by the consumer. The total payment to the pharmacy is typically based on a negotiated contract rate between the pharmacy and the health plan (or the PBM acting on behalf of the health plan). This contract reimburses the pharmacy for its acquisition cost and provides a dispensing fee.

The amount that the consumer or patient pays depends on several factors: (1) the negotiated rate between the plan and pharmacy; (2) the type of drug (i.e., branded or generic); (3) the plan's benefit design (e.g., co-pay or co-insurance); and (4) where the enrollee is within that benefit design at the time of purchase (e.g., in the deductible period, copayment period, MOOP limit or catastrophic phase for those in Medicare Part D). The pharmacy collects the appropriate cost sharing amount from the consumer and receives the remainder from the health plan or PBM at later settlement time based on the payment terms under the contract. (The process described above assumes that there are no manufacturer-sponsored drug coupons and/or co-payment cards, where the manufacturer directly pays a large portion of the consumer's cost sharing. These payment schemes are not operationally transparent to payers, distort an already dysfunctional pricing market, and further complicate a confusing process for consumers.)

Given that the amounts charged by pharmacies for branded drugs reflects the pharmacies' acquisition costs, *these charges are closely correlated to the list price set exclusively by the*

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<sup>22</sup> "Prescription Drug Pricing in the Private Sector," Congressional Budget Office, 2007. <https://www.cbo.gov/sites/default/files/110th-congress-2007-2008/reports/01-03-prescriptiondrug.pdf>

*pharmaceutical manufacturer*. That is why out-of-control drug prices show up at pharmacy counters. It is also why health plans aggressively negotiate with manufacturers for ways to reduce the impact of these prices, so they can pass savings onto consumers. For example, if a health plan's pharmacy and therapeutics committee determines that two or more drugs are therapeutically equivalent and eligible for formulary inclusion, health plans (or PBMs) negotiate with manufacturers for rebates in exchange for plans placing the drugs on a preferred formulary tier and/or waving utilization management tools, such as step therapy protocols. Since drug costs comprise a significant portion of a health plan's total costs, these discounts, which typically take the form of rebates, reduce the net price of the drug.

Rebate amounts typically are calculated and paid by a manufacturer to a health plan on an aggregate basis, long after an individual prescription is filled by a consumer. Because rebates are extended based on actual aggregated utilization by a specific population, they are paid several months after the drug has been prescribed and dispensed and all the data can be reconciled. In designing their plan benefits and developing premium rates in advance of the upcoming coverage year, health plans calculate an estimate of the aggregate rebates they expect to receive. Since drug costs comprise a significant portion of a health plan's total costs, plans may use these estimated discounts to reduce the premiums they charge for the overall benefit. Alternatively, plans may incorporate the estimates into lower point-of-sale pricing for individual drugs that generate the rebates.

By reducing the net price and cost of drugs, all consumers benefit. The savings from discounts and rebates are passed on through improvements to benefit packages, reductions in premiums, and/or lower out-of-pocket costs. This represents a broad and direct benefit for millions of consumers whether they get their coverage through Medicare, on their own, or through their employer.

An example of successful private sector negotiations between health plan sponsors and manufacturers can be found in Medicare Part D. Medicare prescription drug costs have increased by 8 percent annually, from about \$67 billion in 2011 to almost \$100 billion in 2016. During that same time, the average premium paid by beneficiaries only increased by \$2 or about 1 percent annually.<sup>23</sup>

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<sup>23</sup> Medicare Trustees 2017 report. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>

Preserving these health plan practices is essential to supporting market-based solutions, which we discuss in the next section, for providing consumers relief from high prescription drug costs.

### **AHIP’s Recommendations for Reducing Prescription Drug Prices**

The problem with prescription drug pricing does not lie with health plans, wholesalers, pharmacies, providers, or patients. The cost crisis is a direct result of actions by the pharmaceutical industry to take advantage of a broken market. As the committee explores strategies for reducing prescription drug prices, we urge you to consider our recommendations for effective, market-based solutions in three areas: (1) delivering real competition; (2) ensuring open and honest drug pricing; and (3) delivering value to patients. Many of these recommendations were raised in a report recently released by the National Academies of Sciences, Engineering, and Medicine entitled, “Making Medicines Affordable: A National Imperative.”<sup>24</sup>

#### ***Delivering Real Competition***

- **Create a Robust Biosimilars Market:** Biosimilars offer great promise in generating cost savings for consumers. Some of the costliest and most widely-used biologics have been on the market for decades without biosimilar competition. To achieve this promise, it is important to ensure that the FDA promulgates regulations that promote a robust market and ensure providers and patients have unbiased information available to them about the benefits of biosimilars. For example, FDA policies for the labeling, naming, and interchangeability of biosimilars should provide clarity, ensure safety, and avoid unnecessary regulatory hurdles. We also need to address anti-competitive strategies by pharma companies, such as the development of “patent estates,” and tactics aimed at delaying the availability of biosimilars.
- **Reduce Rules, Regulation and Red Tape to Generic Entry:** The FDA should be provided the necessary resources to clear the backlog of generic drug applications, particularly for classes of drugs with no or limited generic competition. To address patent abuses, anti-competitive tactics such as “pay for delay” settlements and “product hopping” should be prohibited, and the Inter Partes Review (IPR) process through the U.S. Patent and Trademark

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<sup>24</sup> National Academies of Sciences, Engineering, and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. <https://doi.org/10.17226/24946>

Office should be preserved. Additional legislation is needed to require brand manufacturers to share information and scientific samples to promote the development of generic drugs.

- **Revisit and Revise Orphan Drug Incentives:** The Orphan Drug Act is being exploited. We urge Congress to ensure that the Orphan Drug Act’s incentives are used by those developing medicines to treat rare diseases – not as a gateway to premium pricing and blockbuster sales beyond orphan indications. In cases of rare diseases for which no effective therapy yet exists, we need to ensure that newly approved drugs are priced in accordance with their efficacy.

### *Ensuring Open and Honest Price Setting*

- **Publish True R&D Costs and Explain Price Setting and Price Increases:** As part of the FDA approval process, manufacturers should be required to disclose information regarding the intended launch price, the use of the drug, and direct and indirect research and development costs. After approval, manufacturers should provide appropriate transparency into list price increases.
- **Limit Third-Party Schemes that Raise Costs:** Policymakers should examine and address the impact of drug coupons and co-pay card programs – and related charitable foundations – on overall pharmaceutical cost trends. These programs often work to steer consumers towards higher priced drugs, and hide the true impact of rising prescription drug costs. It is important to ensure that existing protections aimed at prohibiting their use in certain federal programs are sufficient. In the commercial market, payers need more transparency into when co-pay cards and coupons are being used.
- **Evaluate DTC Advertising Impact:** According to an article in the *Washington Post*, nine out of the ten biggest pharmaceutical companies spend nearly twice as much on sales, marketing, and advertising than they spend on research and development.<sup>25</sup> We urge the committee to assess the impacts of the growth in direct-to-consumer (DTC) advertising, particularly broadcast advertising, and evaluate the best approaches for conveying information to consumers. As part of this assessment, it is important to examine the impact

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<sup>25</sup> “Big pharmaceutical companies are spending far more on marketing than research,” *Washington Post*, February 11, 2015.

of DTC advertising on physician prescribing behavior and/or its effect on generic drug availability and utilization.

### *Delivering Value to Patients*

- **Inform Patients and Physicians on Effectiveness and Value:** Increased funding is needed for private and public efforts to provide information to physicians and their patients on the comparative and cost-effectiveness of different treatments. These tools can help facilitate appropriate assessments about the value and effectiveness of different treatment approaches, particularly those with very high costs. The *New York Times* has highlighted a prime example from one of AHIP’s members that has developed a “counter-detailing” program where the health plan uses representatives who previously worked in the pharmaceutical industry to educate physicians on lower cost but equally effective generic alternatives to high-priced branded drugs.<sup>26</sup>
- **Expand Value-Based Formulary Programs:** It is important to promote value-based payments in public programs like Medicare for drugs and medical technologies, based on agreed-upon standards for quality and outcomes.
- **Reduce Regulatory Barriers to Value-Based Pricing:** We encourage Congress and the Administration to address existing statutory and regulatory requirements (e.g., Medicaid best price rules) that may inhibit the development of pay-for-indication and other value-based strategies in public programs. Specifically, it is important to examine whether Medicaid’s best price requirements are negatively impacting private sector negotiations between plans/PBMs and manufacturers by essentially creating a price floor for prescription drugs.<sup>27</sup>

Thank you for considering our perspectives on these important issues. We are strongly committed to solving the cost crisis. With the right solutions that deliver real competition and create more consumer choices, we can bring down the cost of prescription drugs. We look forward to working with the committee to advance market-based solutions to ensure that consumers have access to affordable medications.

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<sup>26</sup> “Selling Doctors on Cutting Drug Costs,” *New York Times*, June 6, 2017.

<sup>27</sup> “Health Policy Brief: Medicaid Best Price,” *Health Affairs*, August 10, 2017.  
<https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/>