STATEMENT FOR THE RECORD

Submitted to the
Senate Committee on Health, Education, Labor and Pensions

The Cost and Consequences of Rising Prescription Drug Prices

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America’s Health Insurance Plans (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 consumers, 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 consumers.

We appreciate this opportunity to comment on issues surrounding the high cost of prescription drugs and the need for market-based solutions to ensure that consumers have access to affordable medications. We applaud the committee for focusing on this critical issue.

Prescription drug prices are out of control. This starts and ends with the pharmaceutical industry – not others in the distribution system. This is a direct consequence of pharmaceutical companies taking advantage of a broken market for its own gain. When drug companies are effectively granted extraordinary protections through the patent system or market exclusivity protections in federal law, they can set any price they choose – and raise prices at any time for any reason. To put it simply, they have a monopoly on medications. And the result is that everyone pays more, from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

Here are the facts. Launch prices for new drugs continue to rise, particularly in oncology where prices now commonly exceed $10,000 or more for a month of treatment.\(^1\) Just a few years ago, new orphan drugs were typically priced between $250,000 - $300,000 per year. Today, new orphan drugs are commonly priced upwards of three-quarter million dollars.\(^2\)

Out-of-control drug prices are not limited to product launches. Time and time again, manufacturers dramatically increase the price for drugs that have been on the market for years – even decades – with no justifiable reason. And despite growing attention on this issue, the pharmaceutical sector shows no signs of changing its behavior. Just last week it was reported that Pfizer had raised the price of nearly 100 drugs by an average of 20 percent in 2017 alone.\(^3\)


\(^{3}\) “Pfizer Raises US Prices Of 91 Drugs By 20% In 2017,” *Financial Times*, June 2, 2017.
These costs impose a heavy burden on consumers, employers, government programs, taxpayers, and the entire health care system. Why? Because when the cost of delivering medical care— including prescription drugs—goes up, the cost of health insurance goes up. That’s common sense.

EpiPens offer a 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). Had the list price increased by the general rate of inflation (12 percent), a consumer’s co-insurance would have risen by less than $3. That’s the consequence of the cost crisis: hardworking families have less money in their pockets to buy gas, groceries, or save for college or retirement.

To put it another way, according to the most recent Kaiser/HRET data on the annual costs of family coverage by employers, covering the cost of just one new orphan drug is equivalent to the cost of private sector health insurance for an entire year for over 40 families—or more than 160 individuals.

The lack of competition, transparency, and accountability in the prescription drug market has created virtual monopolies that exist nowhere else in the U.S. economy. This must change. With the right solutions that increase competition, choice, and patient control, we can deliver affordable prescription drugs—while protecting and supporting the essential innovations to deliver new treatments and cures for patients.

Our statement focuses on the following topics:

- The consequences out-of-control prescription drug prices have on consumers;
- The actions health plans take to lower prescription drug costs, and how all consumers benefit from these savings through lower premiums and lower out-of-pocket costs; and

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4 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)

5 2016 Employer Health Benefits Survey accessed at http://www.kff.org/health-costs/report/2016-employer-health-benefits-survey/. The annual cost of family coverage is $18,142. Assumes one orphan drug priced at $750,000 annually divided by average annual family premiums in employer-sponsored plans for all plan types (i.e., $750,000 ÷ $18,142) and average family includes four people.
• 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 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 hardworking taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound.

A recent 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.6 Similarly, according to national health expenditure data from the Centers for Medicare & Medicaid Services (CMS), prescription drug spending in 2015 totaled $324.6 billion – a 9 percent increase over 2014 – outpacing the growth rate for all other areas of health care spending. The CMS data were accompanied by a December 2016 article in Health Affairs noting that price growth for existing brand-name drugs reached a double-digit rate in 2015 for the fourth consecutive year – while prices for generic drugs increased less than 1 percent in 2015.7

This is not isolated research on out-of-control prices. Additional evidence includes:

• Orphan Drug Abuse: A recent AHIP data brief found that many drugs classified as orphan drugs are being used to treat common medical conditions, making such medications more expensive for patients and the health care system.8 Our analysis looked at a sample of 45 orphan drugs available from 2012 to 2014 and found that almost half of the utilization of these drugs (44 percent) was for non-orphan diseases. We also found that drugs having little-

6 “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.
to-no orphan utilization increased their prices during this time period by 180 percent more than those orphan drugs used almost exclusively to treat orphan diseases (42 percent versus 5 percent, respectively). These findings demonstrate how many drug companies are manipulating the Orphan Drug Act and its market exclusivity protections to excessively increase prices as part of a scheme to generate blockbuster profits. Our concerns regarding abuse of the Orphan Drug Act have been reinforced by the research of numerous academics, including a study published in the American Journal of Clinical Oncology.9

• **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.10

• **Higher Prices without Better Patient Outcomes:** An April 2015 study by researchers from the National Institutes of Health (NIH) in JAMA Oncology examined 51 oncology drugs approved by the 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.11 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.

• **Shadow Pricing for Older Drugs:** An April 2015 study, published in Neurology, found that the cost of disease-modifying therapies (DMTs) for the treatment of multiple sclerosis increased sharply despite the availability of an increased number of these treatments. Known

as “shadow pricing,” the study noted that older first generation DMTs previously ranged in price from $8,000-$11,000 a year but after “shadow pricing” the newer agents, all DMTs cost upward of $60,000 annually even if they had been on the market for decades.12

- **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 income generated by higher U.S. net drug prices totaled $116 billion in 2015.13 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.”

- **“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.”14 According to a survey by Consumer Reports, many respondents took “potentially dangerous” steps due to 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 groceries, and 15 percent postponed paying other bills so they could afford their prescription drugs.15

These facts paint a clear picture of the crisis we face: drug companies exploit a broken market to price gouge hardworking Americans in need. The root causes are similarly unambiguous: lack

of real market competition due to government-granted monopolies, secret pharmaceutical pricing practices, and no discernible connection between drug prices and the value they deliver to patients.

**Health Plan Protections Help Consumers Understand Their Coverage and Financial Exposure to Rising Drug Costs**

Consumers are taking a more active role in their health decisions, including how to manage the rising prices 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 a recent 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.\(^{16}\) 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 over their coverage.

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, 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.\(^{17}\)

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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 over $100,000 year. 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.

**Health Plans Negotiate Lower Costs – and All Consumers Benefit**

The pharmaceutical industry recently launched a multi-million dollar advertising campaign, and the objective is obvious: to avoid responsibility for out-of-control drug prices. Part of their strategy is to blame others in the distribution system for the consequences of their action. That’s why pharma is shifting attention away from their pricing practices and focusing on the supply chain. It’s also important to remember that a significant portion of drug spending occurs outside of the retail pharmacy supply chain – this includes drugs provided in hospitals, outpatient centers, and physician offices. According to QuintilesIMS, in 2016 non-retail spending represented about 28 percent ($127.3 billion) of the $450 billion in total U.S. drug spending. A similar dynamic can be seen in Medicare. For example, in 2014, Medicare spent $21 billion on Part B drugs – comprising 21% of $99 billion in spending for Medicare Part B and Part D combined. This includes $1.26 billion in Part B spending for Neulasta and $1.24 billion for Remicade. Of further note, pharmaceutical companies do not provide any rebates for the drugs that are covered under Part B. The simple truth is that drug companies set prices high to maximize their profits, while others work hard to bring prices down for consumers.

For example, pharma asserts that health plans do not share with consumers the savings they negotiate with a manufacturer. Pharma argues that consumers are being cheated because health plans do not extend the savings they negotiate to the specific individuals who take a specific drug. The truth is, all consumers benefit from the savings plans negotiate. All consumers pay

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19 Analysis of data from Medicare’s 2015 Drug Spending Dashboard.
less because health plans fight for lower prices – and then pass that savings on in the form of lower premiums and lower out-of-pocket costs for all consumers.

The focus on how savings (typically called “rebates”) are distributed – whether to a small group of patients or across the broader covered population – is a deliberate tactic to avoid addressing 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. The bottom line is, the original list price of a drug – which for many drugs is set not by the market, but solely determined by the drug company – 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.

Because pharma has deliberately shifted the focus away from their egregious pricing practices and to the supply chain, it is important to understand how the supply chain actually works. Manufacturers 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 drug to pharmacies (e.g., smaller community pharmacies) after a small markup above the discounted price.20 This total cost represents the pharmacy’s acquisition cost.

This is when 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 pharmacy benefit manager (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.

What 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., brand or generic); (3) the plan’s benefit design; 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 drugmaker directly pays a large portion of the consumer’s cost sharing. These payment schemes distort an already dysfunctional market and further complicate an already complex, confusing process.)

Given that the amounts charged by pharmacies for brand drugs reflects the pharmacies’ acquisition costs, these charges are closely correlated to the list price set exclusively by the pharmaceutical manufacturer. That’s why out-of-control drug prices show up at pharmacy counters. It is also why health plans aggressively negotiate with manufactures 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 are typically calculated and paid by a manufacturer to a health plan on an aggregate basis, long after an individual prescription is filled by a consumer. Negotiated rebates
for drugs are commonly based on market share calculations for the entire population covered by the health plan. For example, a 15-percent rebate may be extended if the drug attains a 20-percent market share for the relevant market basket (e.g., statins), or a 30-percent rebate for attaining a 40-percent market share. Because rebates are extended based on market performance, 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 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 real and direct benefit for millions of consumers whether they get their coverage through Medicare, on their own, or through their employer.

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

The problem with prescription drug pricing does not lie with health plans, wholesalers, pharmacies, or patients. The cost crisis is a direct result of actions by the pharmaceutical industry to take advantage of a broken market. But what is broken can be fixed. 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.

**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 Food and Drug Administration (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. 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 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 justify list price increases that exceed a percentage threshold.

- **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 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, we 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 do on research and development. 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.

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* recently 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.

- **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.

Thank you for considering our perspectives on these important issues. We are committed – as you are – 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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21 “Big pharmaceutical companies are spending far more on marketing than research,” *Washington Post*, February 11, 2015.