STATEMENT FOR THE RECORD

Submitted to the
Senate Finance Committee

“Prescription Drug Affordability and Innovation: Addressing Challenges in Today’s Market”

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America’s Health Insurance Plans (AHIP) appreciates this opportunity to comment on challenges in the pharmaceutical market and solutions that are needed to help millions of Americans who are burdened by out-of-control prescription drug prices. We thank the committee for calling attention to these important issues and for inviting Secretary Azar to testify on the Trump Administration’s proposals.

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.

As the committee addresses concerns about rising drug prices, 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—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 solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver more affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients. Accessible, affordable medicines are the cornerstone to keeping patients with chronic disease healthier and out of emergency rooms. Reducing the price of medicines is a necessary step toward achieving this goal.

Our statement focuses on the following topics:
• Our initial perspectives on the Trump Administration’s “Blueprint to Lower Drug Prices,” including policies that address the role of Medicare and Medicaid in providing access to affordable medications;

• The consequences that out-of-control prescription drug prices have on consumers; and

• How health plans work hard on behalf of all consumers to negotiate lower prescription drug costs.

**The Trump Administration’s “Blueprint to Lower Drug Prices”**

We commend President Trump and his Administration for focusing on out-of-control prescription drug prices by releasing a “Blueprint for Lower Drug Prices” and publishing a request for information (RFI) that solicits comments from stakeholders and interested parties on policy proposals to lower prescription drug prices and reduce out-of-pocket costs.

We are working closely with AHIP members to develop a formal response to the Administration’s RFI and we will submit comments and recommendations by the July 16 deadline. In the meantime, we want to emphasize that we share the Administration’s goal of getting the most clinically effective drugs into the hands of patients at the lowest cost. Several of the President’s proposed solutions will have a real impact on lowering drug prices for Americans.

We support the Administration’s overall goals of:

• Stopping the pharmaceutical industry from gaming the patent and regulatory systems to keep drug prices high;

• Keeping drug prices from increasing at out-of-control rates;

• Increasing flexibility for insurance providers to negotiate lower drug prices;

• Encouraging doctors to prescribe lower-priced medications; and

• Getting patients clear information about costs as they consider treatments.
To provide consumers relief from high prescription drug costs, AHIP has developed 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. Specific solutions in each of these areas are outlined in an appendix to our statement.

Various elements of the Administration’s Blueprint are aligned with AHIP’s policy recommendations. Below we highlight several examples that offer significant promise for putting downward pressure on prescription drug prices.

**Promote Generic Competition:** We support the Administration’s efforts to prevent brand-name drug manufacturers from using risk evaluation and mitigation strategies (REMS) to block competition from generic drug makers. The Food and Drug Administration (FDA) recently issued two draft guidance documents addressing this priority.

**Promoting Biosimilars:** We support the Administration’s efforts to improve the availability, competitiveness, and adoption of biosimilars as affordable alternatives to branded biologics. We appreciate that these efforts will include steps to educate clinicians, patients, and payors about biosimilar and interchangeable products to increase awareness about these treatments.

**Benefit Flexibility:** We support the Administration’s consideration of a proposal to allow Medicare Part D plans to address price increases for a sole source generic drug through changes to their formulary or benefit design during the coverage year. This flexibility would allow plan sponsors to quickly respond to price increases imposed by the only manufacturer of a generic drug.

**Negotiation Tools:** We support the Administration’s consideration of a proposal to provide Medicare Part D plans with “full flexibility” in using formulary management tools for high-cost drugs for which rebates are often limited or unavailable (e.g., protected class drugs, drugs without competition). These tools, which are widely used in the private sector outside of the Medicare program, would allow plan sponsors to negotiate better drug prices on behalf of Medicare beneficiaries.

**Increased Transparency:** We support the Administration’s release of enhanced CMS Drug Pricing Dashboards for Medicare Part B, Medicare Part D, and Medicaid. The Dashboards can provide patients, families, and caregivers with additional information to make informed decisions and predict their cost-sharing. By increasing transparency, the updated Dashboards have the potential to help hold pharmaceutical manufacturers accountable for drug price
increases, highlight drugs that have not increased in price, and recognize when competition is working.

**Star Ratings:** We support the Administration’s consideration of a proposal to update the methodology used to calculate Drug Plan Customer Service Star Ratings for Medicare Part D plans that are appropriately managing the utilization of high-cost drugs. This would be an important step toward ensuring that Star Rating measures are aligned with the goal of reducing unnecessary use of high-cost drugs.

While the Blueprint and RFI offer mostly positive steps for addressing out-of-control drug prices, we have concerns that several other ideas the Administration appears to be considering would actually lead to higher costs for Americans by weakening the ability of plans to negotiate lower prices. For example, health insurance providers already share the savings from negotiations with drug manufacturers by lowering premiums and cost-sharing for all consumers. However, requiring drug rebates to be passed through at the point-of-sale to individual beneficiaries at the pharmacy counter, rather than be distributed to all enrollees, would likely lead to higher drug prices from manufacturers, higher Part D premiums for all seniors, greater cost-sharing for non-rebated drugs, as well as over $40 billion in additional costs for hardworking taxpayers. Similarly, policies that would eliminate or make it more difficult for plans to negotiate lower prices through rebates without replacing the rebating process with an alternative would similarly drive up costs for all beneficiaries.

On a host of other issues, we are continuing to hold discussions and solicit feedback from AHIP work groups to develop detailed recommendations for HHS. We look forward to working together with the Administration, Congress, and other stakeholders to lower drug prices through market-based solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices that are driven by their value 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

1 *FY 2019 Budget in Brief* (page 61), Department of Health and Human Services.  
used for salaries to pay for more expensive prescriptions, 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.

A May 2018 AHIP analysis concluded that 23.2 cents out of every premium dollar goes to pay for prescription drugs—making this the largest component of health care spending.\(^2\) Our analysis found that prescription drug spending outpaces the amount spent on physician services, office and clinic visits, and hospital stays. 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.

Even for products that have been on the market for decades, sharp price increases are not uncommon. One study shows that the price of insulin has increased more than 240 percent over the past decade; for example, the price of Lantus increased from $88.20 per vial in 2007 to $307.20 per vial in late 2017, while the price of Levemir increased from $90.30 per vial to $322.80 per vial during the same time period.\(^3\) These sharp price increases harm patients and reduce the affordability of coverage for all consumers and payers who must bear the cost through higher insurance premiums.

A June 2018 report from the Department of Health and Human Services’ (HHS) Office of Inspector General (OIG) found that unit costs for brand-name drugs in the Medicare Part D program rose nearly six times faster than inflation from 2011 to 2015, with the average Part D unit cost increasing 29 percent over this time frame.\(^4\)

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The HHS OIG report identifies 20 brand-name drugs that experienced the largest percentage increases in Part D unit costs from 2011 to 2015. This includes six drugs with unit cost increases of more than 4,000 percent and four other drugs with unit cost increases exceeding 2,000 percent. For example:

- Isordil Titradose, used to treat angina, increased by 6,112 percent from 2011 to 2015;
- Timentin, used to treat infections, increased by 4,661 percent;
- Levsin, used to treat irritable bowel syndrome, increased by 4,212 percent;
- Salex, used to treat skin disorders, increased by 4,202 percent;
- Miacalcin, used to treat osteoporosis, increased by 2,771 percent;
- Thiola, used for kidney stone prevention, increased by 2,465 percent; and
- Cuprimine, used to treat rheumatoid arthritis, increased by 2,143 percent.

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

- **Price Inflation is a Primary Cost Driver:** Segal Consulting, a prominent benefits 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.\(^5\) 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.\(^6\)

- **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

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\(^6\) Ibid.
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.7

- **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 2015.8 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.9 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—a practice known as “shadow pricing”—rather than the value or the improved outcomes they deliver to patients.

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7 *Trends in Hospital Inpatient Drug Costs: Issues and Challenges*, NORC, October 11, 2016. [http://www.aha.org/content/16/aha-fah-rx-report.pdf](http://www.aha.org/content/16/aha-fah-rx-report.pdf)
• “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.” The difficulty in affording unreasonably priced prescription drugs can lead to treatment non-adherence, which can harm patient health creating adverse outcomes and lead 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 groceries, and 15 percent postponed paying other bills so they could afford their prescription drugs.

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.

While some have tried to divert attention away from high prescription drug prices and, instead, point to others in the supply chain—namely, pharmacy benefit managers (PBMs) and rebates—as the source of the problem, we should focus on how the supply chain actually functions and the true root of the cost crisis when evaluating policy options.

The Role of Health Plans in Negotiating Lower Costs for All Consumers

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 PBMs and negotiating with drug and device manufacturers, pharmacies, physicians, and hospitals to ensure that enrollees have coverage for the treatments and services they need.

While prescription drug pricing and the pharmaceutical supply chain are complex, health plans are still, on the whole, able to successfully navigate the system and provide significant savings. Health plans aggressively negotiate with drug manufacturers for lower prices—and then pass those savings directly on in the form of both lower out-of-pocket costs and lower premiums for all consumers.

Health plans negotiate for price concessions from manufacturers, just as they do with providers. Health plans leverage competition between manufacturers to drive deeper discounts in exchange for preferred formulary placement and lower cost-sharing for their products, just as they do with providers. However, in discussing how plans obtain discounts from manufacturers, it is important to understand the role rebates play within the broader system and why the rebate structure is used to obtain cost savings for pharmaceuticals rather than the “negotiated rates” typically used to obtain savings for health services.

Though not broadly understood, plans do not directly reimburse pharmaceutical manufacturers for their products even though they do negotiate directly for price concessions. Instead, distributors and some large pharmacies and health systems directly purchase drugs from manufacturers. The price paid by these entities is highly correlated to the list price set by the manufacturer with only modest discounts based on volume or prompt pay. Distributors resell pharmaceutical products to smaller and mid-sized pharmacies and providers after a small markup above the discounted price.12 Finally, plans directly reimburse pharmacies or providers (depending on where the drug is obtained) once a claim is filed and any consumer cost-sharing obligations are accounted for.

Since pharmacies and providers obtain drugs at or near the list price, plans must also reimburse them at (or very close to) this rate, plus an additional negotiated add-on fee to ensure these entities are not “underwater” for their purchase. Because there is no interaction between plans and manufacturers at the point-of-sale, all price concessions must come after the fact through rebates. These rebate amounts are typically calculated and paid by a manufacturer to a health plan on an aggregate basis, accounting for all fulfilled claims for a product, long after an individual prescription is filled by a consumer.

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. They also incorporate the savings into the overall cost-sharing design for the benefit, including for individual rebated drugs. Plan benefit design and premiums are heavily regulated by state departments of insurance and/or the Centers for Medicare & Medicaid Services (CMS). By contrast, pharmaceutical manufacturers are not subject to any governmental oversight or regulation before setting list prices or pushing through price increases.

It is important to understand that while plans are able to negotiate significant price concessions from manufacturers, this only applies to a subset of drugs that have therapeutic alternatives. For most branded drugs and biologics without therapeutic alternatives, manufacturers’ willingness to negotiate on price is small or nonexistent and they have no rebates. Evidence shows that the percentage of rebated drugs is decreasing and that list prices are also consistently rising whether drugs are rebated or not. In fact, the recent HHS OIG report states: “Total reimbursement for all brand-name drugs in Part D increased 77 percent from 2011 to 2015, despite a 17-percent decrease in the number of prescriptions for these drugs… After accounting for manufacturer rebates, reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015… In addition, the percentage of brand-name drugs for which manufacturers paid rebates decreased [over this period].”

Further, rebates are not commonly found for physician-administered drugs, which account for 30 percent of prescription drug spending.

The bottom line is that, whether a drug is rebated or not, the original list price of a drug drives costs in the entire system. This price is solely determined and controlled by the drug company, 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.

Conclusion

Thank you for considering our perspectives on these important issues. We are strongly committed to solving the pharmaceutical 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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Appendix: AHIP Recommendations to Reduce Drug Prices and Costs

Rising prescription drug costs hurt everyone. From patients who cannot access breakthroughs and consumers who pay higher and higher premiums to taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound. Pharmacy now accounts for approximately 23 percent of all medical spending. We need effective market-based solutions that deliver real competition, create more consumer choice, and ensure that open and honest drug prices are driven by the value they bring to patients.

Solution #1: Real Competition
✓ **Create a Robust Biosimilars Market:** Ensure that providers and patients have unbiased information available to them about the benefits of biosimilars. Address anti-competitive strategies, such as the development of “patent estates,” and tactics aimed at delaying the availability of biosimilars. Policies for labeling, naming, and interchangeability should provide clarity, ensure safety, and avoid unnecessary regulatory hurdles.
✓ **Reduce Rules and Red Tape to Generic Entry:** Provide FDA with 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 should be preserved. Legislation requiring brand manufacturers to share needed information and samples to promote generic development should be advanced.
✓ **Revisit and Revise Orphan Drug Incentives:** 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, ensure that newly approved drugs are priced in accordance with their efficacy.

Solution #2: Open and Honest Price Setting
✓ **Publish Rx Prices, True R&D Costs, and Price Increases:** As part of the FDA approval process, require that manufacturers disclose information regarding intended launch price, use, and direct and indirect R&D costs. After approval, require manufacturer reporting of list price increases over a percentage threshold amount that explains why such price increases are justified.
✓ **Limit Third-Party Schemes that Raise Costs:** Examine and address the impact of drug coupons and co-pay card programs—and related charitable foundations—on overall pharmaceutical cost trends. Ensure that existing protections aimed at prohibiting their use in all federal programs are sufficient.
✓ **Evaluate DTC Advertising Impact:** Assess impacts of the growth in direct-to-consumer (DTC) advertising, particularly broadcast advertising, and evaluate the best approaches for conveying information to consumers.

Solution #3: Delivering Value to Patients
✓ **Inform Patients on Effectiveness and Value:** Increase funding for private and public efforts to provide information on the comparative and cost-effectiveness of different treatments to physicians and their patients. These tools can help them make appropriate assessments about the value and effectiveness of different treatment approaches, particularly those with very high costs.
✓ **Expand Value-Based Formulary Programs:** 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:** Address existing statutory and regulatory requirements (e.g., Medicaid best price) that may inhibit the development of pay-for-indication and other value-based strategies in public programs.