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December 8, 2017

Maureen K. Ohlhausen  
Acting Chairwoman  
Federal Trade Commission  
400 7<sup>th</sup> Street, SW  
Washington, DC 20024

*Submitted electronically*

**Re: Federal Trade Commission Workshop on Understanding Competition in  
Prescription Drug Markets: Entry and Supply Chain Dynamics—AHIP Comments**

Dear Acting Chairwoman Ohlhausen:

On behalf of America's Health Insurance Plans (AHIP), we applaud the Federal Trade Commission (FTC) for holding last month's public workshop—*Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics*—and appreciate the FTC's focus on examining competition in prescription drug markets. AHIP is pleased to offer comments addressing the need to promote greater competition in prescription drug markets to reduce costs and promote access to more affordable medications and treatments for patients.

AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day, including coverage for prescription drugs to consumers and beneficiaries in the individual market and employer-sponsored plans, Medicare Advantage and Part D, and Medicaid managed care plans. 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.

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.<sup>1</sup> According to the Centers for Medicare and Medicaid Services (CMS), “prescription drug spending growth is anticipated to accelerate from 5.7 percent in 2017 to an average of 7.0 percent from 2018-2019.”<sup>2</sup> Moreover,

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<sup>1</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>2</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>

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according to official estimates from CMS, prescription drug spending is projected to grow an average of 6.3 percent per year from 2016 to 2025<sup>3</sup>—with total prescription drug spending reaching \$597.1 billion by 2025.<sup>4</sup>

According to the Milliman Medical Index—a widely used benchmark for estimating health care costs for 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>5</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>6</sup> Similarly, 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.<sup>7</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>8</sup>

Simply put, prescription drug prices are out of control, and this is a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies that exist nowhere else in the U.S. economy. When drug companies are allowed to effectively extend and abuse the exclusivity provided under patent law or other federal laws, they prevent competitors from entering the market and protect their ability to obtain monopoly rents. The end result is that everyone pays more—from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

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 hardworking taxpayers who fund public programs like Medicaid and Medicare, the consequences are profound.

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<sup>3</sup> National Health Expenditure Projections 2016-2025 *Forecast Summary* <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/proj2016.pdf>

<sup>4</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>5</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>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> Segal Consulting--High Rx Cost Trends Projected to Be Lower for 2018. Fall 2017.

<sup>8</sup> Ibid.

The broad 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>9</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.
- **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>10</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 income generated by higher U.S. net drug prices totaled \$116 billion in 2015.<sup>11</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

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<sup>9</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>10</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>

<sup>11</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/>

*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.<sup>12</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>13</sup> According to another 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.<sup>14</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 bear the staggering costs. The root causes are similarly unambiguous: lack of real market competition due to the extension and distortion of government-granted exclusivity and patent protections, opaque pharmaceutical pricing practices, and limited correlation between drug prices and the value they deliver to patients.

Within this context, we applaud the FTC’s focus on the critically important issue of promoting greater competition in the prescription drug marketplace—as a way to both reduce costs and improve access to drugs and treatments. We offer our comments and recommendations in the following key areas—

- Identifying existing barriers to competition in the prescription drug market—including the negative impact of policies that reduce generic and biosimilar drug competition that can reduce costs for patients and consumers;

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<sup>12</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>13</sup> Kaiser Health Tracking Poll: September 2016. <http://www.kff.org/health-costs/report/kaiser-health-tracking-poll-september-2016/>

<sup>14</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>

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- Describing the role private health plans play in reducing prescription drugs costs and limiting consumers' financial exposure to rising drug costs; and
- Providing market-based policy recommendations to reduce prescription drug costs—with a focus on the important role of the FTC in addressing anti-competitive practices and lowering costs.

### **I. Barriers to Competition in the Prescription Drug Marketplace that are Fueling High Drug Prices**

Out-of-control growth of prescription drug spending is driven by the anticompetitive extension and abuse of monopolies and other anticompetitive behavior. Below are some common strategies that are being used to delay the entry of generic drugs, block competition, and extend the life of patents—all with the end goal of protecting monopoly pricing by branded pharmaceuticals at the expense of the entire health care system.

- **Abuses of FDA REMS Programs and Private Restricted Distribution Systems:** Since the introduction of Risk Evaluation and Mitigation Strategies (REMS), branded manufacturers have increasingly exploited the rules surrounding the distribution restrictions to thwart access to samples of their original product from generic developers, even if the Food and Drug Administration (FDA) has certified that the sale of samples would not be in violation of a REMS program. If generic or biosimilar developers are denied the ability to conduct bioequivalence testing of original products due to anticompetitive activities, the developers are essentially prevented from developing a generic or biosimilar version and bringing it to market.

At a March 2017 congressional hearing, an FDA official testified that the agency had received over 150 inquiries from generic developers unable to access samples of original products.<sup>15</sup> This method of restricting access to samples has evolved to the point where branded manufacturers are now moving to limit the distribution of their product *outside* of FDA REMS programs through private restricted distribution systems. In fact, it was one of the tactics used by Turing Pharmaceuticals to limit the availability of their life-saving product, Daraprim.<sup>16</sup>

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<sup>15</sup> U.S. Congress, House Committee on Oversight and Government Reform, Subcommittee on Health Care, Benefits and Administrative Rules, *Examining the Impact of Voluntary Restricted Distribution Systems in the Pharmaceutical Supply Chain*, 115<sup>th</sup> Congress, March 22, 2017.

<sup>16</sup> Pollack, Andrew. "New York Attorney General Examining Whether Turing Restricted Drug Access," *New York Times*, October 12, 2015.

A recent study estimated the total sales for products subject to FDA REMS restricted distribution systems and private restricted distribution systems to be over \$20 billion in 2016.<sup>17</sup> A 2014 analysis estimated that, of 40 drugs on the market in 2014 for which generic developers reported their inability to get access to samples, \$5.4 billion could have been saved in *annual* drug spending if those generic versions were on the market.<sup>18</sup>

- **“Evergreening” of Patent Protections:** There is growing evidence that prescription drug manufacturers are gaming patent protections to artificially prolong the exclusivity period for some drugs and prevent less costly generic versions from reaching the market.<sup>19</sup> By making minor changes to a drug’s chemical composition or delivery mechanism (e.g., an extended release version of a previously patented drug that had to be taken twice daily), manufacturers can extend patents that otherwise would have expired. These “evergreening” schemes do not typically provide any enhanced clinical benefit to consumers – rather they are aimed at maintaining monopolistic pricing for products that are just as effective as their less expensive, generic counterparts. Related anti-competitive strategies such as “product hopping” – when pharmaceutical manufacturers withdraw a certain drug from the market and introduce a newer version with minor changes in an effort to delay the entry of a generic substitute – frustrate efforts to realize savings from generic drugs. Strategies like these have resulted in a market for insulin – a drug widely available for the last 90 years – where the only available options are brand-name versions costing hundreds of dollars per vial.<sup>20</sup>
- **Prescription Co-Pay Programs:** Drug manufacturers often point to coupons or co-pay cards as a method for helping patients afford their prescriptions. While drug co-pay coupons can reduce out-of-pocket costs for specific (likely branded) drugs for individual consumers, they actually artificially inflate costs for everyone by hiding the true impact of rising costs. According to an article published in the *New England Journal of Medicine*, co-pay programs are a “triple boon” for manufacturers because “they increase demand, allow companies to charge higher prices, and provide public relations benefits.”<sup>21</sup>

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<sup>17</sup> Brill, Alex. “REMS and Restricted Distribution Programs: An Estimate of the Market,” Matrix Global Advisors, June 2017.

<sup>18</sup> Brill, Alex. “Lost Prescription Drug Savings from Use of REMS Programs to Delay Generic Market Entry,” Matrix Global Advisors, July 2014.

<sup>19</sup> Collier, Roger. “Drug patents: the evergreening problem,” CMAJ/ JAMC, June 2013. Vernaz, Nathalie, et. al. “Patented Drug Extension Strategies on Healthcare Spending: A Cost-Evaluation Analysis.” PLOS Medicine, June 2013. Kesselheim, Aaron. “Rising Health Care Costs and Life-Cycle Management in the Pharmaceutical Market.” PLOS Medicine, June 2013.

<sup>20</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>21</sup> Howard, David H. “Drug Companies’ Patient-Assistance Programs—Helping Patients or Profits?” *New England Journal of Medicine*. 2014: 371:97-99, July 10, 2014.

- **“Pay-for-Delay” Agreements:** Anticompetitive settlements with generic manufacturers that prevent generics from entering the market in a timely manner cost consumers and the health system. A staff study compiled by the FTC concluded that “‘Pay for delay’ agreements are a ‘win-win’ for the companies: brand name pharmaceuticals stay high, and the brand and generic share the benefits of the brand’s monopoly profits.”<sup>22</sup> The FTC estimated that these agreements are costing consumers \$3.5 billion per year. The Congressional Budget Office estimated that prohibiting these settlements would save the federal government \$3 billion over ten years and would accelerate the availability of lower-priced generic drugs.<sup>23</sup>
- **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.<sup>24</sup>
- **Orphan Drug Abuse:** An 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.<sup>25</sup> 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-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.

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<sup>22</sup> Federal Trade Commission Staff Study. “Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions,” January 2010.

<sup>23</sup> Congressional Budget Office Cost Estimate: S. 2019, Preserve Access to Affordable Generics Act. October 20, 2015.

<sup>24</sup> Hartung, et al. “The Cost of Multiple Sclerosis Drugs in the U.S. and the Pharmaceutical Industry,” *Neurology*, April 4, 2015.

<sup>25</sup> “Orphan Drug Utilization and Pricing Patterns (2012-2014),” AHIP, October 2016. Orphan drugs are defined as those intended to treat rare diseases that affected fewer than 200,000 people in the United States.

## **II. Health Plan Role in Reducing Prescription Drug Costs—Including Negotiating Discounts and Debates**

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 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>26</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 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 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>27</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 over \$100,000 year.<sup>28</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

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<sup>26</sup> “Characterizing Health Plan Price Estimator Tools: Findings From a National Survey,” Higgins A, Brainard N, Veselovskiy G., *AJMC*, February 2016.

<sup>27</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>28</sup> “High Priced Drugs: Estimates for Annual Per-Patient Expenditures for 150 Specialty Medications,” AHIP, April 2016.

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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.

### *The Role of Rebate Negotiation in Reducing Prescription Drug Costs*

The FTC roundtable featured numerous stakeholder and expert testimony about the role of intermediaries—including pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs). While prescription drug pricing in the private sector is complex, 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 that 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. 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.

Unfortunately, there has been effort underway by manufacturers of branded drugs and biologics to divert attention from high prescription drug prices and instead point to problems in the drug supply chain and role of wholesalers and PBMs. However, it is important to understand 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 drug to pharmacies (e.g., smaller community pharmacies) after a small markup above the discounted price.<sup>29</sup> This total cost represents the pharmacy’s acquisition cost.

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<sup>29</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>

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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 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., branded 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 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 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.

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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. 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% 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% annually.<sup>30</sup>

Preserving these health plan practices – including both negotiation of lower prices and medical management programs that improve patient care – are essential to supporting market-based solutions, which we discuss in the next section, for providing consumers relief from high prescription drug costs. 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.

### **III. Policy Recommendations to Reduce Prescription Drug Costs**

As the FTC 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.

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<sup>30</sup> Medicare Trustees 2017 report. <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2017.pdf>

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### 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. In addition, state pharmacy laws should support a robust biosimilars market in the same manner that so successfully supported the development of a generics market. 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 challenged by the FTC, 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. The Orphan Drug Act’s incentives should only be 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>31</sup> Further assessment is needed of the impacts of the growth in direct-to-consumer (DTC) advertising, particularly broadcast advertising, followed by an evaluation the best approaches for conveying information to consumers. As part of this assessment, the FTC could examine the impact 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>32</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, FTC can examine whether Medicaid’s best price requirements are negatively impacting private sector negotiations between

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<sup>31</sup> “Big pharmaceutical companies are spending far more on marketing than research,” *Washington Post*, February 11, 2015.

<sup>32</sup> “Selling Doctors on Cutting Drug Costs,” *New York Times*, June 6, 2017.

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plans/PBMs and manufacturers by essentially creating a price floor for prescription drugs.<sup>33</sup>

In addition, we believe the FTC should continue to play its important role in vigorously investigating and challenging anti-competitive behavior that leads to higher prices for consumers and in advocating for state and federal policies that are supportive of competitive pharmaceutical markets. Among the areas in which even more FTC enforcement and advocacy would be beneficial are:

- “Pay-for-delay” settlements that prevent generics from entering the market in a timely manner;
- Abuses of regulatory processes, such as FDA citizen petitions, to prolong drug monopolies;
- Product hopping, where manufacturers withdraw a certain drug from a market and introduce a newer version with minor changes to prevent the entry of a generic substitute;
- Product evergreening, where manufacturers make minor updates to an existing product to extend patent protections; and,
- Abuses of prescription drug co-pay coupons and patient assistance programs (PAPs), for example their use to undermine generic competition.

Thank you for considering our perspectives on these important issues. We look forward to working with the FTC and engaging in a dialogue with all stakeholders to advance market-based solutions to ensure that consumers have access to affordable medications.

Sincerely,

  
Matthew Eyles  
Senior Executive Vice President & Chief Operating Officer

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<sup>33</sup> “Health Policy Brief: Medicaid Best Price,” *Health Affairs*, August 10, 2017.  
<https://www.healthaffairs.org/doi/10.1377/hpb20171008.000173/full/>