



December 8, 2017
Federal Trade Commission
Office of the Secretary
Room H-113 (Annex X)
600 Pennsylvania Avenue NW
Washington, DC 20850PhRMA

Re: Workshop on Understanding Competition in Prescription Drug Markets

Dear Sir or Madam:

Thank you for the opportunity to participate in the workshop on November 8 entitled, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." Understanding the role the drug delivery system plays in determining what patients pay for medicines is a critical part of the discussion about what can be done to improve patient access and affordability and I appreciated the opportunity to explore this topic at the workshop.

PhRMA represents the country's leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. The biopharmaceutical sector is one of the most research-intensive industries in the U.S.: since 2000, PhRMA member companies have invested more than half a trillion dollars in the search for new treatments and cures, including \$65.5 billion in 2016 alone.

In addition to the comments set forth below related to Panel 2, we have attached Follow the Dollar: Understanding How the Pharmaceutical Distribution and Payment System Shapes the Prices of Brand Medicines. This paper provides an overview and several illustrative examples of the financial flows for brand medicines. We have also attached PhRMA's November 17, 2017 comments to FDA on "Administering the Hatch-Waxman Amendments: Ensuring a Balance Between Innovation and Access." These comments address and respond to many of the issues raised during Panel 1 of the Workshop.

The Competitive Market for Prescription Medicines Balances Innovation, Patient Access, and Cost Containment

The competitive market is the engine that drives the innovative biopharmaceutical research and development ecosystem. The dynamics of the private, market-based system in the U.S. promote incentives for continued innovation and patient access to needed medicines while leveraging competition to achieve cost containment. Since 2000, biopharmaceutical companies have brought more than 500 new medicines to the U.S. market, resulting in significant progress against some of the most costly and challenging diseases.¹ Through innovation, the death rate for HIV/AIDS has dropped 86% and more recently, decades of work are paying off in cancer as new therapies launched over the

¹ US Food and Drug Administration. Summary of NDA Approvals & Receipts, 1938 to the Present. <http://www.fda.gov/aboutfda/whatwedo/history/productregulation/summaryofndaapprovalsreceipts1938tothepresent/default.htm>; US Food and Drug Administration. New Drugs at FDA: CDER's New Molecular Entities and New Therapeutic Biological Products. 2012 – 2015. <https://www.fda.gov/drugs/developmentapprovalprocess/druginnovation/default.htm>

past few years are recognized as game changers that are transforming the treatment of many cancers. Today, because of scientific advances many other conditions are now manageable and sometimes even curable. Yet, as a result of robust negotiation and competition in the marketplace, spending on medicines is growing at the slowest rate in years.²

Government, market analyst, and pharmacy benefit manager data all point to the same conclusion: that after peaking in 2014—an anomaly year in which millions of uninsured patients gained coverage and a record number of new medicines were approved—prescription drug spending growth has fallen substantially. National health expenditure data just released show that retail prescription medicine spending grew more slowly than overall health care cost growth in seven of the last ten years, and grew just 1.3% in 2016, less than one third of the rate of overall health care spending growth.³ Accounting for discounts and rebates, multiple other sources report historically low growth rates.⁴ As a result of negotiation and competition in the marketplace, spending on retail and physician-administered medicines continues to represent only 14% of overall health care spending, even though scores of new medicines are approved every year. And at the state level, Medicaid programs spent just 4.9% of their budgets on prescription drugs, including new medicines, in 2016, relative to 26% for hospital care and 18.2% for provider services.⁵

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The U.S. biopharmaceutical marketplace promotes innovation and affordability through cost containment that is built into the prescription drug lifecycle. While the price of a medicine may increase or decrease over its lifetime, prices fall dramatically as competition occurs among brand-name medicines, and typically fall even further (up to 80%) with the introduction of generics.⁶ For instance, the price of one common statin (atorvastatin, known in the branded form as Lipitor) used to lower cholesterol and prevent cardiovascular disease, dropped by about 92% from 2005 to 2013 when generic alternatives came to market.⁷ Meanwhile, the average charge for percutaneous transluminal coronary angioplasty (PTCA) – a surgical procedure to treat cardiovascular disease – increased by almost 66% during that same time period.⁸

² QuintilesIMS Institute. Medicine Use and Spending in the US: A Review of 2016 and Outlook to 2021. April 2017

³ Hartman M, Martin AB, Espinosa N, Catlin A, et al. National Health Spending in 2016: Spending and Enrollment Growth Slow After Initial Coverage Expansions. *Health Affairs*. 2018;37(1) Available online ahead of print at <https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2017.1299>.

⁴ QuintilesIMS Institute. Medicine Use and Spending in the US: A Review of 2016 and Outlook to 2021. April 2017; CVS Health. CVS Health PBM Clients Achieved Lowest Prescription Drug Trend in Four Years, Despite Rising Drug Prices. March 15, 2017. <http://www.prnewswire.com/news-releases/cvs-health-pbm-clients-achieved-lowest-prescription-drug-trend-in-four-years-despite-rising-drug-prices-300423726.html>; Express Scripts. 2016 Drug Trend Report. February 2017. <https://lab.express-scripts.com/lab/drug-trend-report>; Which PBM Best Managed Drug Spending in 2016: How Did OptumRx Compare? Drug Channels. April 25, 2017. <http://www.drugchannels.net/2017/04/which-pbm-best-managed-drug-spending-in.html#more>.

⁵ Prescription drug pre-rebate expenditures tabulated by The Menges Group using FY2016 CMS State Drug Utilization data files and CMS brand/generic indicators for each National Drug Code. Rebate information obtained from FY2016 CMS-64 reports. Post-rebate expenditures derived through The Menges Group tabulations using above information.

⁶ IMS Institute for Healthcare Informatics. Price Declines After Branded Medicines Lose Exclusivity in the US January 2016.

⁷ Atorvastatin, known in the branded form as Lipitor 10mg: IMS National Sales Perspective (NSP) Invoice Price in 2005 (Branded Lipitor) and in 2013 (Generic Atorvastatin).

⁸ Data adapted from: HCUP Hospital Charge Database 2005 to 2013, Average Hospital Charges.

The U.S. market is structured to take maximum advantage of savings from brand competition and from generics. Three large, sophisticated pharmacy benefit managers (PBMs) manage about 70% of all prescriptions filled.⁹ They use brand competition to obtain discounts from manufacturers and take full advantage of the presence of generics to drive savings. This drives the rapid shift of market share to generics (and, looking forward, to biosimilars), a system with few analogues in other health care sectors. As one example of the growing influence of PBMs, industry leader Express Scripts has publicly stated their success in leveraging substantial rebates for hepatitis C medicines led to those treatments being less expensive in the U.S. than in many other western countries.¹⁰ And the competitive market will continue to generate savings in the years ahead, as more than \$140 billion of U.S. brand sales are projected to face generic competition between now and 2021.¹¹ Competition from biosimilars is estimated to account for \$38 billion of the loss in brand spending.

List Prices for Medicines Do Not Reflect Substantial Rebates and Discounts and Provide an Increasingly Inaccurate Picture of Prescription Drug Costs

Much of the public debate about the cost of medicines has focused on list prices, which do not account for the rebates and discounts that PBMs and health plans commonly negotiate with biopharmaceutical companies in exchange for preferred formulary placement on lower cost-sharing tiers. For certain medicines used to treat chronic conditions like asthma, high cholesterol, hepatitis C, and diabetes, these discounts and rebates can reduce list prices by as much as 30% to 70%.¹² Biopharmaceutical companies are also required to provide sizable statutory rebates, discounts, and fees to government programs, which have increased in recent years due to an increase in the Medicaid rebate, closing of the Medicare Part D “donut hole” and expansion of the 340B program. These mandatory payments grew by more than 40% between 2013 and 2015, increasing from \$29.6 billion to \$41.8 billion.¹³

Excluding rebates and discounts from discussions about the cost of prescription medicines provides an increasingly inaccurate picture of marketplace trends. According to PBMs and industry analysts, list prices for brand medicines have grown by an estimated 9% to 12% annually since 2015, while net prices (which take discounts and rebates into account) have grown by just 2.5% to 3.5%.¹⁴ A recent study from

⁹ Fein AJ; Drug Channels Institute. The 2017 economic report on U.S. pharmacies and pharmacy benefit managers. Exhibit 72. February 2017.

¹⁰ LaMattina J. For Hepatitis C Drugs, U.S. Prices Are Cheaper Than in Europe. *Forbes*. December 4, 2015. <http://www.forbes.com/sites/johnlamattina/2015/12/04/for-hepatitis-c-drugs-u-s-prices-are-cheaper-than-in-europe/#7ced43f564bb>

¹¹ QuintilesIMS Institute. Medicine Use and Spending in the US: A Review of 2016 and Outlook to 2021. April 2017.

¹² QuintilesIMS Institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016; Gronholt-Pedersen J, Skydsgaard N, Neely J. Novo Nordisk Defends U.S. Diabetes Drug Pricing. *Reuters*. November 4, 2016. <http://www.reuters.com/article/us-novo-nordisk-prices-idUSKBN12Z184>; Silverman E. What the ‘Shocking’ Gilead Discounts on its Hepatitis C Drugs Will Mean. *Wall Street Journal*. February 4, 2015. <https://blogs.wsj.com/pharmalot/2015/02/04/what-the-shocking-gilead-discounts-on-its-hepatitis-c-drugs-will-mean/>; Barrett P, Langreth R. The Crazy Math Behind Drug Prices: Intermediaries that Negotiate to Lower Prices May Cause Them To Increase Too. *Bloomberg Businessweek*, June 29, 2017. <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices>

¹³ Berkeley Research Group. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholder. January 2017.

¹⁴ QuintilesIMS Institute. Medicine Use and Spending in the US: A Review of 2016 and Outlook to 2021. April 2017; Express Scripts. 2016 Drug Trend Report. February 2017. <https://lab.express-scripts.com/lab/drug-trend->

the QuintilesIMS Institute demonstrates that net prices for medicines that have been on the market for at least two years *declined* by an average of 2.5% annually from 2010 to 2016, driven by patent expirations and increased competition from generics.¹⁵ The QuintilesIMS report also notes that over the next five years, net prices for existing medicines will continue to decline between 1% and 4% annually, highlighting the important role rebates and discounts will continue to play in containing prescription medicine spending growth in the future.

Claims from PBMs, payers, and others about the skyrocketing prices of medicines almost always focus solely on list prices, which are not reflective of actual spending trends. When new hepatitis C medicines offering cure rates exceeding 90% entered the market, PBMs claimed that these life-saving treatments and cures would bankrupt the health system and their costs were simply unsustainable. Instead, competition among brand manufacturers quickly drove deep discounts averaging 40% to 65% off the list price.¹⁶ Express Scripts now states that their aggressive negotiations have saved Americans \$4 billion, cured more patients with hepatitis C than any time in history, and that the discounted price makes it affordable to treat all patients with the infection.¹⁷

Prior to the launch of PCSK9 inhibitors, a new type of cholesterol lowering medicine that represents a significant advance in treatment of heart disease, PBMs made alarming claims about their cost, projecting up to \$150 billion to \$200 billion per year in spending for these medicines.¹⁸ The Centers for Medicare and Medicaid (CMS) Office of the Actuary, however, projected a much more modest impact, based on expected competition leading to discounts and continued widespread use of generic statins.¹⁹ The Actuary's refusal to accept these inflated claims proved to be the right approach. In fact, PBMs quickly made deals to cover both of the brand competitors on the market and emphasized that the drugs' cost is "far lower than industry forecasts."²⁰ New research shows that PBMs have also effectively used strict prior authorization and high cost-sharing requirements to suppress utilization of these medicines, resulting in less than one-third of patients prescribed a PCSK9 inhibitor being able to access therapy.²¹

A Complex Distribution and Payment System Shapes the Prices Patients, Health Plans, and the Government Pay for Medicines

report; SSR Health. US Brand Pharmaceutical Net Prices Fell 0.3% in 3Q16. January 18, 2017.

<http://www.ssrllc.com/publication/us-brand-pharmaceutical-net-prices-fell-0-3-in-3q16/>

¹⁵ QuintilesIMS Institute. Understanding the Drives of Drug Expenditure in the US. September 2017.

¹⁶ What Gilead's Big Hepatitis C Discounts Mean for Biosimilar Pricing. Drug Channels. February 5, 2015.

<http://www.drugchannels.net/2015/02/what-gileads-big-hepatitis-c-discounts.html>

¹⁷ Express Scripts. The \$4 Billion Return on a Promise Kept. January 27, 2015. [http://lab.express-](http://lab.express-scripts.com/lab/insights/specialty-medications/the-4-billion-return-on-a-promise-kept)

[scripts.com/lab/insights/specialty-medications/the-4-billion-return-on-a-promise-kept](http://lab.express-scripts.com/lab/insights/specialty-medications/the-4-billion-return-on-a-promise-kept)

¹⁸ Shrank W, Lotvin A, Singh S, Brennan T. In the Debate About Cost and Efficacy, PCSK9 Inhibitors May Be The Biggest Challenge Yet. *Health Affairs Blog*. February 17, 2015. <http://healthaffairs.org/blog/2015/02/17/in-the-debate-about-cost-and-efficacy-pcsk9-inhibitors-may-be-the-biggest-challenge-yet/>

¹⁹ Kelly C. U.S. Drug Spending Will Increase 7.6% in 2015, Including PCSK9 Costs – CMS. *The Pink Sheet*, July 2015.

²⁰ Express Scripts. "Express Scripts Includes Innovative Cholesterol-Lowering Drugs on National Preferred Formulary." October 6, 2015. <http://www.prnewswire.com/news-releases/express-scripts-includes-innovative-cholesterol-lowering-drugs-on-national-preferred-formulary-300155222.html>

²¹ Navar AM, Taylor B, Mulder H, et al. Association of Prior Authorization and Out-of-Pocket Costs With Patient Access to PCSK9 Inhibitor Therapy. *JAMA Cardiology*. Published online September 27, 2017. doi:10.1001/jamacardio.2017.3451.

The process by which prescription medicines move from biopharmaceutical manufacturers to patients involves multiple stakeholders and numerous financial transactions. This process has evolved significantly in recent years, as supply chain entities have grown to play a larger role in drug distribution and payment. Wholesalers, pharmacies, plan sponsors, and patients all pay different prices for medicines, and the amount that is ultimately paid is determined by confidential negotiations between stakeholders. Many discounts provided by manufacturers do not flow directly through to the patients taking the medicine, and in some cases the full discounts may also not flow through to employers or plan sponsors.²²

Some manufacturer rebates and discounts are required by law, while others are negotiated between biopharmaceutical companies and powerful commercial payers, many of which cover tens of millions of patients. In recent years, as payers have consolidated and competition between brand medicines has increased, negotiated rebates and discounts have also grown. Multiple data sources indicate that growth in manufacturer rebates and discounts has been substantial and that an increasing share of these discounts and rebates are retained by middlemen involved in distributing and paying for prescription medicines.²³ According to a recent study by the Berkeley Research Group, on average, more than a third of the initial list price of a medicine is rebated back to insurance companies, PBMs and the government, or retained by other stakeholders along the biopharmaceutical supply chain.²⁴ And the gap between list prices and net prices is growing every year as more of medicine costs are being retained by middlemen in the system.

As shown in Figure 1, accounting for the discounts, rebates and fees paid to PBMs, payers, and the government, brand biopharmaceutical companies realize less than half of total net spending on prescription medicines.²⁵ Of the \$469 billion spent on prescription drugs in the U.S. in 2015, brand manufacturers realized \$219 billion; the remainder went to generic manufacturers or was retained as earnings by entities along the supply chain and other stakeholders.²⁶ The \$219 billion realized by the brand biopharmaceutical industry accounts for just 6.8% of the \$3.2 trillion spent on health care overall in the U.S. in 2015.²⁷

²² Midwestern Business Group on Health. Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies. September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf

²³ QuintilesIMS Institute. Medicine Use and Spending in the US: A Review of 2016 and Outlook to 2021. April 2017; Berkeley Research Group. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholder. January 2017; Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? Mercer. July 31, 2017. <https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>

²⁴ Berkeley Research Group. The Pharmaceutical Supply Chain: Gross Drug Expenditures Realized by Stakeholder. January 2017.

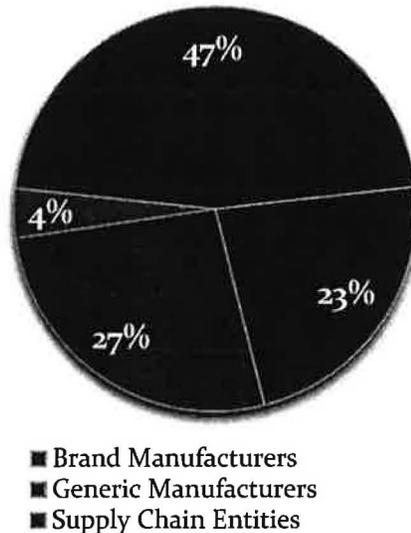
²⁵ *Ibid.*

²⁶ *Ibid.*

²⁷ Martin AB, Hartman M, Washington B, et al. National Health Spending: Faster Growth in 2015 As Coverage Expands and Utilization Increases. *Health Affairs*. 2017;36(1):166-176.

Figure 1:

Share of 2015 Net Prescription Medicine Spending Realized by Manufacturer and Non-Manufacturer Stakeholders



Patients Do Not Directly Benefit from Significant Price Negotiations Happening in the Market Today

Savings generated from price negotiations between biopharmaceutical companies and payers do not always make their way directly to patients facing high cost-sharing for their medicines. Unlike care received at an in-network hospital or physician's office, health plans base cost-sharing for prescriptions filled in the deductible or with coinsurance on undiscounted list prices, rather than on prices that reflect negotiated rebates and discounts. Enrollment in high deductible health plans and use of coinsurance for prescription medicines has grown sharply in recent years, increasingly exposing patients to high out-of-pocket costs based on undiscounted prices, creating scenarios in which medicines appear to be more costly than other health care services. High cost-sharing is a cause for concern, as a substantial body of research clearly demonstrates that increases in out-of-pocket costs are associated with both lower medication adherence and increased abandonment rates, putting patients' ability to stay on needed therapies at risk.²⁸

Over the past 10 years, patient cost-sharing has risen substantially faster than health plan costs. For workers with employer-sponsored health insurance, out-of-pocket spending for deductible and coinsurance payments increased by 230% and 89%, respectively, compared to a 56% increase in

²⁸ IMS Institute for Healthcare Informatics. Emergency and Impact of Pharmacy Deductibles: Implications for Patients in Commercial Health Plans. September 2015; Doshi JA, Li P, Huo H, et al. High Cost Sharing and Specialty Drug Initiation Under Medicare Part D: A Case Study in Patients with Newly Diagnosed Chronic Myeloid Leukemia. *American Journal of Managed Care*. 2016;22(4 Suppl):S78-S86; Brot-Goldberg ZC, Chandra A, Handel BR, et al. What Does A Deductible Do? The Impact of Cost-Sharing on Health Care Prices, Quantities, and Spending Dynamics. NBER Working Paper 21632, October 2015; Eaddy MT, Cook CL, O'Day K, et al. How Patient Cost-Sharing Trends Affect Adherence and Outcomes. *Pharmacy & Therapeutics*. 2012;37(1):45-55.

payments by health plans.²⁹ Whereas cost-sharing for prescription medicines once consisted almost entirely of copays, use of deductibles and coinsurance has increased rapidly particularly for new medicines that represent the most innovative therapies and treat the sickest patients. The share of patient out-of-pocket drug spending represented by coinsurance more than doubled over the past ten years in the commercial market, while the share accounted for by deductibles tripled.³⁰

The growing use of deductibles and coinsurance for prescription medicines creates affordability challenges for many patients. Patients enrolled in high deductible health plans may be asked to pay thousands of dollars out-of-pocket before any of their prescriptions are covered, while patients with coinsurance are responsible for as much as 30% to 40% of the total cost of their medicines.

Due to the growing gap between list and net prices, patients' cost sharing for medicines is increasingly based on prices that do not reflect plan sponsors' actual costs. For example, market analysts report that negotiated discounts and rebates can lower the net price of insulin by up to 50% to 70%, yet health plans require patients with deductibles to pay the full undiscounted price. As a result, a patient in a high-deductible health plan who pays the list price each month for insulin maybe paying hundreds—or even thousands—more annually than their insurer.

As a hypothetical example, imagine a patient taking an insulin with a list price of \$400. The patient's insurer may have negotiated a 65% rebate, which is not uncommon for insulins. Since the insurer does not pay anything until the patient meets his deductible, and the patient's bill reflects the full cost. But despite paying nothing for the medicine, the insurer still collects the rebate, earning over \$200.³¹ Unfortunately, as the number of patients with deductibles and coinsurance rises, this situation is becoming more common. Analysis by Amundsen Consulting shows that more than half of patients' out-of-pocket spending for brand medicines is based on the list price of the medicine, even though their health insurer may be receiving a steep discount.³²

Health plans typically use some portion of negotiated rebates to reduce premiums for all enrollees, rather than to directly lower costs for patients facing high cost-sharing due to deductibles and coinsurance. According to one actuarial firm, this results in a system of "reverse insurance," whereby payers require patients with high drug expenditures to pay more out-of-pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.³³ Asking sicker patients with high drug costs to subsidize premiums for healthier enrollees is the exact opposite of how health insurance is supposed to work.

²⁹ Claxton G, Levitt L, Long M, et al. Increases in Cost-Sharing Payments Have Far Outpaced Wage Growth. Peterson-Kaiser Health System Tracker. October 4, 2017. <https://www.healthsystemtracker.org/brief/increases-in-cost-sharing-payments-have-far-outpaced-wage-growth/#item-start>

³⁰ Claxton G, Levitt L, Long M. Payments for Cost Sharing Increasing Rapidly Over Time. Peterson-Kaiser Health System Tracker. April 2016. <http://www.healthsystemtracker.org/insight/examining-high-prescription-drug-spending-for-people-with-employer-sponsored-health-insurance/>

³¹ Pharmaceutical Research and Manufacturers of America. Follow the Dollar. November 2017. <http://phrma-docs.phrma.org/files/dmfile/Follow-the-Dollar-Report.pdf>

³² Amundsen Consulting. Commercially-Insured Patients Pay Undiscounted List Prices for One In Five Brand Prescriptions, Accounting for Half of Out-of-Pocket Spending on Brand Medicines. March 2017. <http://www.phrma.org/report/commercially-insured-patients-pay-undiscounted-list-prices-for-one-in-five-brand-prescriptions-accounting-for-half-of-out-of-pocket-spending-brand-medicines>

³³ Girod CS, Hart SK, Weltz S. 2017 Milliman Medical Index. May 2017. <http://www.milliman.com/uploadedFiles/insight/Periodicals/mmi/2017-milliman-medical-index.pdf>

Some patients also end up paying more at the pharmacy counter when they use their insurance, not knowing that their prescriptions would be cheaper if they were paying in cash. Many PBM contracts require pharmacies to charge patients the exact amount negotiated between the PBM and the pharmacy, even if that amount exceeds what the pharmacy would charge to a patient without insurance. Gag-clauses in PBM contracts prohibit pharmacists from informing insured patients about the lower cash price, at the risk of the pharmacy being excluded from the PBM's network. In these instances, pharmacies must instead overcharge patients, requiring them to pay the full amount of their copayment, over and above the actual cost of the medication. These overpayments are then "clawed back" from the pharmacy by the PBM.³⁴

PBMs Negotiate Lower Medicine Prices for Health Plans and Employers, But Don't Always Pass Along All of the Savings

PBMs commonly retain a portion of the rebates they negotiate on behalf of their health plan and employer clients. While the remainder of the rebates are generally passed on to plan sponsors, smaller employers and health plans may not benefit from all of the price concessions the PBM has negotiated with manufacturers, particularly if the PBM decides not to define certain fees or other concessions as "rebates." For example, one benefits consultant has observed that PBMs are increasingly changing the contractual definition of rebates to exclude certain administrative fees, allowing the PBM to retain these payments rather than passing them back to the plan sponsor. These administrative fees can be as high as 25% to 30% of the total rebate negotiated with the manufacturer and are often not reported to the plan sponsor by the PBM.³⁵

In addition to the rebates they negotiate with biopharmaceutical companies, PBMs are increasingly requiring that if a medicine's list price increases by more than a certain percentage, the manufacturer must provide an additional price protection rebate reimbursing the PBM for all price increases above the threshold. Lack of transparency in contracts between employers and PBMs has led many plan sponsors to question the share of rebate savings being passed through, how much the PBM is retaining for administrative fees, and whether the PBM is disclosing and passing on other price concessions, such as savings from price protection rebates.³⁶

Both the portion of the rebate retained by the PBM and the administrative fees they charge their clients are typically based on a percentage of a medicine's list price. Accordingly, some PBMs may prefer that their formularies include medicines with high list prices and large rebates, rather than medicines with a lower list price. Thus if a manufacturer were to lower the list price of a medicine in lieu of a higher rebate, the PBM's revenue would decline. Because PBMs hold the key to market access through their decisions about formulary coverage and placement, such a manufacturer decision could result in reduced formulary access.

³⁴ Hopkins JS. You're Overpaying for Drugs and Your Pharmacist Can't Tell You. *Bloomberg*. February 24, 2017. <https://www.bloomberg.com/news/articles/2017-02-24/sworn-to-secrecy-drugstores-stay-silent-as-customers-overpay>

³⁵ Dross D. Will Point-of-Sale Rebates Disrupt the PBM Business? *Mercer*. July 31, 2017.

<https://www.mercer.us/our-thinking/healthcare/will-point-of-sale-rebates-disrupt-the-pbm-business.html>

³⁶ Midwestern Business Group on Health. Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies. September 2017. https://higherlogicdownload.s3.amazonaws.com/MBGH/4f7f512a-e946-4060-9575-b27c65545cb8/UploadedImages/Specialty%20Pharmacy/DMJ_MBGH_Line_in_the_Sand_RV12_9617.pdf

In its most recent report to Congress, the Medicare Payment Advisory Commission discussed incentives that may drive Part D plan sponsors to give formulary preference to medicines with large rebates, rather than lower cost alternatives.³⁷ These incentives arise because sizable portions of the Part D benefit are not paid for by plan sponsors (e.g., beneficiaries and manufacturers pay for the majority of costs in the coverage gap). Similarly, CMS has noted that coverage of medicines with high list prices and large rebates “ease[s] the financial burden borne by Part D plans essentially by shifting costs to the catastrophic phase of the benefit, where plan liability is limited”³⁸ and that plans have “weak incentives, and in some cases even, no incentive, to lower prices at the point of sale or to choose lower net cost alternatives to high cost-highly rebated drugs when available.”³⁹ Recently, CMS addressed this concern in a Request for Information issued as part of a proposed regulation for Medicare Part D. In an effort to better align plan incentives with the interests of beneficiaries and the Medicare program, CMS is soliciting feedback on a potential future proposal to require Part D plans to share negotiated rebate savings directly with beneficiaries at the point of sale.

Addressing Distorted Incentives by Sharing Negotiated Savings with Patients

Changes in insurance coverage for prescription medicines, and the growing use of deductibles and coinsurance in particular, have created affordability challenges for many patients. Health plans should be encouraged to directly pass on more of the savings from negotiated rebates in the form of lower patient out-of-pocket costs, just like they do for other types of health care services. This should be executed in a way that maintains the confidentiality of proprietary pricing information that the Federal Trade Commission has identified as important to the effective functioning of competitive markets. Payers have begun to recognize that using the undiscounted price of a medicine to set cost-sharing is problematic for patients: recent statements from the two largest PBMs note that high deductibles for medicines put patients in a “very difficult position” and indicate that sharing rebate savings directly with patients should be considered as a “best practice.”⁴⁰ Actuarial research indicates that sharing negotiated savings could save certain commercially insured patients enrolled in plans with high deductibles and coinsurance between \$145 and \$800 annually, while increasing premiums by 1% or less.⁴¹

To help patients afford their medicines, biopharmaceutical companies have entered into partnerships with third parties, such as Blink Health and GoodRx, to offer discounted prices directly to patients, outside of their insurance benefit.⁴² Encouraging health plans to allow the cost of prescriptions purchased through these third-party programs to count towards patients’ deductibles and maximum out-of-pocket spending limits would further reduce patient affordability barriers.

³⁷ Medicare Payment Advisory Commission. Status Report on the Medicare Prescription Drug Program (Part D). March 2017. http://medpac.gov/docs/default-source/reports/mar17_entirereport.pdf

³⁸ Centers for Medicare & Medicaid. Medicare Part D—Direct and Indirect Remuneration (DIR). January 19, 2017. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html>

³⁹ 82 FR 56419 (November 28, 2017)

⁴⁰ Seeking Alpha. Express Scripts Holding (ESRX) Q4 2016 Results – Earnings Call Transcript. February 15, 2017. <http://seekingalpha.com/article/4046365-express-scripts-holding-esrx-q4-2016-results-earnings-call-transcript>; Seeking Alpha. CVS Health (CVS) Q4 2016 Results – Earnings Call Transcript. February 9, 2017. <http://seekingalpha.com/article/4044425-cvs-health-cvs-q4-2016-results-earnings-call-transcript?part=single>

⁴¹ Bunger A, Gomberg J, Petroske J. Sharing Rebates May Lower Patient Costs and Likely Has Minimal Impact on Premiums. October 12, 2017. <http://www.phrma.org/report/point-of-sale-rebate-analysis-in-the-commercial-market>

⁴² Thomas K. New Online Tools Offer Path to Lower Drug Prices. *New York Times*. February 9, 2016. <https://www.nytimes.com/2016/02/10/business/taming-drug-prices-by-pulling-back-the-curtain-online.html>

Copay assistance programs offered by biopharmaceutical companies provide another valuable source of assistance for many commercially insured patients who are struggling to afford their out-of-pocket costs, as do manufacturer-sponsored patient assistance programs that help underinsured and uninsured patients obtain the medicines they need for free or nearly free. Recent efforts by health plans to restrict use of copay assistance programs, including no longer counting the full amount patients are asked to pay out-of-pocket towards their deductibles or out-of-pocket maximums, unfairly penalize patients and threaten their ability to stay on needed medicines.

Market-Based Approaches Are the Best Solution for Addressing Health Care Affordability and Controlling Costs

Today's pharmaceutical distribution and payment system is complex, but by almost any measure it is very successful. It delivers roughly six billion prescriptions to patients every year, and generates deep discounts which have held growth in prescription drug costs in check; drug costs grew more slowly than overall health care costs in seven out of the last 10 years.

Nevertheless, it is clear that the system needs to serve patients better, and that incentives could be better aligned across all stakeholders to assure efficient market competition. We need to make sure that the system is working for patients, and that savings provided by manufacturers find their way to patients and can help reduce patient cost sharing. Meaningful efforts to address the cost of prescription medicines must include all stakeholders in the supply chain, including biopharmaceutical companies, PBMs, health plans, wholesalers, hospitals, and pharmacies. Policies targeted solely at brand manufacturers—which account for just half of total net spending on prescription medicines and just 6.8% of total U.S. health care spending—are insufficient for addressing broader health care sustainability challenges and risk diminishing the incentives for future innovation.

Strategies for strengthening and enhancing the competitive market include:

- Encouraging payers to share negotiated savings with patients at the pharmacy;
- Supporting best practices of employers and payers to improve information and accountability in their contracts with PBMs;
- Facilitating evolution of privately negotiated payment arrangements by updating regulations that currently hinder market adoption of indication-based pricing, outcomes-based contracts, and other value-based contracts between payers and manufacturers;
- Reforming the 340B drug discount program, which is distorting incentives in the market and failing to serve the purpose for which it was created; and
- Continuing to modernize the Food and Drug Administration (FDA) in order to assure robust generic and biosimilar competition once a brand medicine loses its exclusivity.

Looking ahead, it is clear that medicines offer some of the clearest opportunities to address the challenge of growing health care costs as our population ages. For example, the number of Alzheimer's cases is projected to increase rapidly over the next decade as Baby Boomers begin to reach retirement age, resulting in an enormous human and economic cost. If we can achieve treatment advances that delay Alzheimer's by just five years beginning a decade from now, 2.5 million fewer Americans will be afflicted by the disease and we would avoid \$367 billion annually by 2050 in costs for long-term care and

similar services for persons with Alzheimer's.⁴³ Alzheimer's remains a major focus of biopharmaceutical research companies despite high risks; since 1998 there have been 123 unsuccessful attempts to develop a medicine for Alzheimer's, and just four approved medicines.⁴⁴ In just the last two years, several promising new therapies failed in mid- and late-stage trials, resulting in the loss of billions of dollars of human, political, and monetary capital.⁴⁵ This underscores the extraordinary risk biopharmaceutical companies confront to bring new treatments to market.

PhRMA appreciates the FTC's effort to solicit input on the pharmaceutical supply chain. We hope these comments will inform your deliberations. If you have any questions, please contact us.

Respectfully submitted,


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⁴³ Alzheimer's Association. "Changing the Trajectory of Alzheimer's Disease: How a Treatment by 2025 Saves Lives and Dollars." https://www.alz.org/documents_custom/trajectory.pdf

⁴⁴ PhRMA. *Researching Alzheimer's Medicines: Setbacks and Stepping Stones*. Summer 2015. Available at: <http://phrma.org/sites/default/files/pdf/alzheimers-setbacks-and-stepping-stones.pdf>

⁴⁵ Ogg JC. The List of Failed Alzheimer's Drug Treatments Keeps Growing. 24/7 Wall Street. September 26, 2017. <http://247wallst.com/healthcare-business/2017/09/26/the-list-of-failed-alzheimers-drug-treatments-keeps-growing/>