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**Hearing on “Improving Drug Pricing Transparency and
Lowering Prices for American Consumers”**

**United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Health
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Good morning and thank you Chairwoman Eshoo, Ranking Member Burgess, and distinguished Members of the Subcommittee for inviting the Pharmaceutical Research and Manufacturers of America (PhRMA) to testify at today’s hearing. I am Lisa Joldersma, Senior Vice President at PhRMA, and I am honored to be here before you today.

At biopharmaceutical companies across America, people go to work every day with the mission of advancing innovative treatments and cures that will make a difference in millions of patients’ lives. Since 2000, PhRMA’s member companies have invested half a trillion dollars in the search for innovative treatments and cures,ⁱ including more than \$71 billion in 2017 alone. These investments have helped transform the way we think about disease prevention and management, and in recent years have brought forth curative therapies and pioneering approaches to defeating sickness and disease. Today there are about 7,000 medicines in development.ⁱⁱ Of those medicines in the pipeline, an estimated 74 percent have the potential to be first-in-class treatments.ⁱⁱⁱ

These innovations typically happen through years of collaborative biomedical research, with biopharmaceutical companies playing a central role. The level of risk undertaken by biopharmaceutical innovators often is overlooked, but the fact is that just 12 percent of medicines entering clinical trials are ultimately approved by the Food and Drug Administration (FDA). In other words, almost 9 in 10 fail – and this excludes all the candidates that never even reach the clinical trial stage. One estimate of the cost to develop a new medicine projects it to be \$2.6 billion when accounting for the need to recoup the cost of failures.

Continued advances in medicines are indispensable to addressing some of our society's biggest health and economic challenges. While medicines' role in effective health care has grown and many new treatments and cures have been brought to patients over the years, medicines have remained a consistent 14 percent of total United States (U.S.) health spending.^{iv} However, even though net costs for brand medicines are growing at the slowest rate in years, patients often are unable to access the therapies they need due to cost burden.

Many factors impact what a patient pays for medicine. A product's list price – or “wholesale acquisition cost” – is one factor, but other factors are also important, including insurance plan design, formulary placement, and whether there are assistance programs available. PhRMA applauds the subcommittee for ongoing interest in making prescription drugs more accessible and affordable for all Americans. PhRMA shares that goal. Thank you for bringing a broad range of stakeholders to the table for these important discussions – both today and at last week's hearing.

Transparency

Several of the measures highlighted for discussion today call for greater transparency from manufacturers and pharmacy benefit managers. PhRMA supports greater transparency across the health care market. In fact, we have taken steps – voluntarily – to provide public access to information that patients may need or want when making health care decisions. Our Medicine Assistance Tool, or MAT, is an online platform that complements our member companies' new approach to direct-to-consumer (DTC) television advertising announced in October 2018. As part of this effort, the PhRMA board of directors adopted enhancements to its voluntary DTC principles to state that “[a]ll DTC television advertising that identifies a prescription medicine by name should include direction as to where patients can find information about the cost of a medicine, such as a company-developed website, including the list price and average, estimated, or typical patient out-of-pocket costs, or other context about the potential cost of the medicine.” MAT provides patients, caregivers and providers with links to these new websites and includes a search engine to connect patients with medicine-specific financial assistance programs. In addition, MAT has resources to help patients navigate their insurance coverage, found at www.MAT.org.

PhRMA recognizes that many policymakers have already taken steps towards legislating greater transparency for manufacturers. We would not presume that MAT is a substitute for those approaches or that it will satisfy individual every member's goals. We do hope, however, that it demonstrates the sincerity with which PhRMA enters this discussion. We are committed to working with Congress to take meaningful steps to address patient concerns.

When considering legislative approaches to transparency – including the several states that have passed or considered transparency measures – three, high-level questions help shape PhRMA's thinking. First, is the proposal likely to yield information that will be meaningful or useful to patients? Second, does the proposal give individual manufacturers clear notice about the scope of information at issue and would it be reasonable to implement? And third, is there adequate protection for confidential and proprietary information or could there be unintended consequences in the market as a result of the disclosure of certain types of information? PhRMA also strongly believes that transparency efforts should look beyond manufacturers and consider the role several other entities play in shaping drug spending, including pharmacy benefit managers (PBMs), health insurers, and even hospitals.

Additional reforms needed to promote affordability for patients

Greater transparency can help promote better decision making and affordability, but two additional – and more significant – issues could negatively impact affordability for patients: misaligned incentives in the prescription drug distribution and payment system, and increased shifting of costs onto patients.

Many Patients Do Not Directly Benefit from Significant Price Concessions in the Market Today

Since the beginning of the Medicare Part D program in 2006, it has been a resounding success. According to Congressional Budget Office (CBO) estimates, total Part D costs were 45 percent (\$349 billion) lower than projected for the initial 2004 to 2013 forecast period.^v Average monthly beneficiary premiums are \$32.50 in 2019,^{vi} substantially lower than the \$54.47 originally projected.^{vii} Powerful Part D purchasers negotiate discounts and rebates with manufacturer and the Medicare Trustees report that “many brand-name prescription drugs carry substantial rebates,”^{viii} which have increased each year of the program.^{ix} However, patients do not always benefit directly from these rebates in the form of lower cost sharing, resulting in

affordability challenges for some Part D beneficiaries taking brand-name medicines with large manufacturer discounts.

To improve patient affordability, more of the discounts and rebates insurers and PBMs negotiate with biopharmaceutical companies should be shared directly with patients at the point-of-sale. Once medicines are researched, developed, and approved for use, 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. In fact, three large, sophisticated PBMs manage more than 75 percent of all prescriptions filled.^x They use brand competition to obtain discounts from manufacturers and take full advantage of the presence of generics to drive savings. In fact, the use of generic medicines, which accounts for 90 percent of prescription medicines dispensed in the U.S., saved \$1.79 trillion between 2008 and 2017,^{xi} and these dynamics will continue to produce savings. Between 2019 and 2023, competition from generics and biosimilars is expected to result in an estimated \$105 billion reduction in U.S. brand sales.^{xii} Additionally, biosimilar competition in the biologics market will increase substantially over time as the market matures.^{xiii} There is no similar type of cost containment for other health care services.

Consolidation and increased negotiating power give middlemen like PBMs leverage to extract growing price concessions from manufacturers. The magnitude of these rebates, discounts, and other reductions in price have more than doubled since 2012, totaling over \$166 billion in 2018.^{xiv} 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 percent.^{xv} According to a study by the Berkeley Research Group, on average, more than one-third of the initial list price of a brand medicine is rebated back to insurance companies, PBMs, and the government, or retained by other stakeholders along the biopharmaceutical supply chain.^{xvi}

Even though payers often receive deep discounts on a brand medicine's price, they rarely directly pass along those savings to the patients obtaining those medicines at the pharmacy counter. Instead, health plans typically use some portion of negotiated rebates to reduce premiums for all enrollees. As the actuarial firm Milliman has pointed out, this dynamic results

in a system of “reverse insurance” where payers require sicker patients using brand medicines with rebates to pay more out-of-pocket, while rebate savings are spread out among all health plan enrollees in the form of lower premiums.^{xvii} Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the opposite of how health insurance is supposed to work.

This problem is particularly striking for patients with diabetes taking insulin. Robust competition among insulin manufacturers has resulted in increasing levels of discounts and rebates that have kept net prices flat to declining over the past several years.^{xviii} That is because payers leverage competition among a broad range of long-, short-, rapid-acting insulin to negotiate lower prices. These dynamics can lower the net price of insulin by 70 percent or more.^{xix, xx} Although media reports commonly give the false impression that biopharmaceutical companies retain all revenue from list price increases, flat net price growth indicates that all or almost all of insulin list price increases are returned to payers, the government, and other medicine supply chain entities through rebates, fees, or other discounts.

While robust competition in the market has been successful in constraining net prices for insulins, government and industry analysts have observed that supply chain intermediaries may have incentives to favor medicines with high list prices and large rebates,^{xxi} leading to affordability challenges for patients who pay cost sharing based on the list price. Helping patients access the treatments they need by passing through rebates at the point-of-sale to reduce patient cost sharing could improve medicine adherence for conditions like diabetes, which could ultimately generate savings by reducing costly avoidable health complications. A recent study by IHS Markit found that passing through a share of rebates to Medicare Part D patients taking diabetes medicines could reduce overall health care spending (including spending in Parts A and B) for Medicare beneficiaries with diabetes by \$20 billion over the next 10 years.^{xxii}

A proposed rule from the U.S. Department of Health and Human Services’ (HHS) Office of the Inspector General (OIG)^{xxiii} is an important step towards an improved Part D program. OIG reports that, on average, Medicare Part D beneficiaries who do not receive low-income subsidies (LIS) would pay 10 to 19 percent less in cost sharing over the next 10 years under the Administration’s proposed system to encourage upfront discounts.^{xxiv} And patients who take brand medicines with relatively large rebates, such as medicines for diabetes, would be likely to

see larger-than-average reductions in out-of-pocket costs because they would now directly benefit from those rebates.^{xxv}

The principles underlying the OIG’s proposed rule to reform the rebate system could restore payers’ incentives to favor lower cost medicines while strengthening incentives to negotiate deep discounts on medicines. In the absence of the existing rebate system, Part D plans would still have strong incentives to minimize costs. As Milliman notes, plans would be incentivized to achieve lower net costs to minimize premium increases and maintain LIS auto-enrollment.^{xxvi} Actuaries have also suggested that under the changes proposed by the OIG, some manufacturers “may have more success marketing biosimilars in Part D if manufacturer rebates are eliminated,” due to the incentives for plans to achieve lower net costs.^{xxvii}

Increased Cost-Shifting to Patients

A growing distortion in the market is the increased shifting of costs to patients. Patients pay cost sharing for health care services, including prescription medicines, through deductibles, copays, and coinsurance. When a patient fills a prescription in the deductible phase, the patient pays the entire list price of the medicine up to the deductible amount. Patients with copays pay a fixed amount for each prescription (e.g., \$30), while those with coinsurance pay a percentage of the medication’s total list price (e.g., 30 percent).

In the last decade, in the commercial market, the share of patient out-of-pocket drug spending represented by coinsurance has more than doubled, while the share accounted for by deductibles has tripled.^{xxviii} Since 2006, deductibles for patients in employer health plans have increased by 300 percent.^{xxix} Patient out-of-pocket spending on coinsurance has increased 67 percent while spending on copays has decreased.^{xxx} The share of employer health plans requiring a deductible for prescription medicines has more than doubled from 23 percent in 2012 to 52 percent in 2017.^{xxxi} As one recent analysis shows, patients are required to pay 12 percent of overall pharmaceutical costs versus only 4 percent of hospital costs – even though medicines can help keep patients out of the hospital.^{xxxii}

Deductibles and coinsurance leave patients with high and often unpredictable costs, particularly for their medicines. Average commercially insured patient out-of-pocket costs for deductible and coinsurance claims for brand medicines are much higher than copay claims.^{xxxiii} In 2017,

more than half of commercially insured patients' out-of-pocket spending for brand medicines was for medicines filled while a patient was in the deductible or with coinsurance, an increase of 20 percent from 2013.^{xxxiv} Patients with chronic conditions are disproportionately impacted by high out-of-pocket costs.^{xxxv}

In Medicare Part D, there has been a substantial increase in the use of coinsurance and complex, multi-tiered formularies. Today, 93 percent of stand-alone Part D plans (PDPs) use formularies with five coverage tiers, and 7 percent are now using a sixth tier.^{xxxvi} The percentage of Part D drugs subject to coinsurance jumped by nearly 20 percentage points between 2016 and 2019. Today, 62 percent of all medicines covered by PDPs are covered on a coinsurance tier.^{xxxvii}

When patients receive medical care from an in-network hospital or physician, deductible and coinsurance payments are based upon discounted rates negotiated between the health plan and the provider. Yet this is not the case for prescription medicines. Health plans (and the PBMs that represent them) negotiate discounts on brand medicines, but the discounts are usually given in the form of rebates paid directly to the health plan or PBM after the prescription is purchased by the patient. These discounted prices are not available to patients with deductibles or coinsurance at the time they fill prescriptions; instead, their cost sharing is generally calculated by the health plan based on the medicine's full list price.

Research shows that rebates paid by biopharmaceutical companies often substantially reduce the list prices of brand medicines.^{xxxviii} However, since list prices do not reflect rebates, these savings are not directly passed on to patients through lower cost sharing, and patients' out-of-pocket costs for prescriptions filled in the deductible or with coinsurance are higher than they otherwise would be if instead they were based on the discounted cost of the medicine. Thus, the growing use of deductibles and coinsurance for medicines has exposed patients to undiscounted list prices and created affordability challenges for many.^{xxxix}

As the Subcommittee continues its work on policy solutions to help drive greater transparency and prescription drug affordability, we hope there remains an unwavering commitment to biomedical innovation. We urge the Committee to avoid overly broad policies that may seem designed to "shame" manufacturers while doing little to make prescriptions more affordable for

patients. PhRMA appreciates the opportunity to testify and looks forward to continuing to engage with the Committee on these critically important issues.

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- ^{viii} See 2018 Medicare Trustees Report, p. 144, footnote 66.
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