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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 \$900 billion in the search for innovative treatments and cures,ⁱ including more than \$79.6 billion in 2018 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.

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.

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.ⁱⁱ In 2018, net prices for brand-name medicines increased 0.3% on average, less than the rate of inflation.ⁱⁱⁱ 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 important, including insurance plan design, formulary placement, and whether there are assistance programs available.

Before turning to pricing issues, I wanted to briefly touch on what medicines are accomplishing. Medicines play a central role in transforming the trajectory of many debilitating diseases, resulting in decreased death rates, improved health outcomes, and better quality of life for patients.

- *Cardiovascular disease*: Tremendous strides have been made against cardiovascular disease over the past 40 years, due in large part to advances in treatment. Since 1980 alone, the death rate from heart disease has declined by nearly 60 percent.^{iv} And between 1980 and 2000, approximately two-thirds of the decline in coronary heart disease mortality, the most common type of heart disease, is attributable to medical therapies.^v
- *HIV/AIDS*: Once considered acutely fatal, HIV/AIDS is now a chronic and manageable disease. This dramatic change followed the introduction of highly effective antiretroviral therapy in the mid-1990s, which transformed treatment and led to an 88 percent decline in death rates in the United States.^{vi}

- *Hepatitis C*: More recently, we've seen a remarkable transformation in treatment of another viral disease: hepatitis C. Just six years ago, the only available treatment cured just half of patients and caused debilitating side effects. Today, a broad range of treatments with minimal side effects and cure rates approaching 100 percent are available for patients with all forms of the disease.^{vii,viii} Looking forward, researchers project that with improved screening and today's cures, hepatitis C will be a rare disease by 2036.^{ix}
- *Cancer*: New medicines are also a driving force behind gains in the life expectancy of cancer patients. Since peaking in the early 1990s, cancer death rates in the United States have declined 26 percent.^x Researchers attribute 73 percent of these gains to new treatments, including new medicines.^{xi} Targeted therapies and emerging immunotherapies are transforming the treatment paradigm for patients with many forms of cancer and have the potential to reduce the use of traditional forms of cancer treatment—including chemotherapy, surgery, and radiation.^{xii}

Researchers are pursuing cutting-edge research and novel scientific strategies to continue to drive therapeutic advances for patients. There are currently about 7,000 medicines in clinical development globally with the potential to impact U.S. patients.^{xiii} Across the medicines in the pipeline, 74 percent have the potential to be first-in-class treatments.^{xiv} Diseases and conditions for which medicines are in development include:^{xv}

- *Neurological disorders*: These disorders affect a broad range of conditions affecting the brain and nervous system—for example, epilepsy, migraine headaches, multiple sclerosis, Parkinson's disease, and Alzheimer's disease. There are more than 500 medicines in development for neurological disorders. One exciting cell therapy approach for amyotrophic lateral sclerosis (ALS) involves extracting stem cells from patient bone marrow and customizing the cells to help support the survival of neurons once the cells are returned to the patient.^{xvi}
- *Cancer*: In addition to the adaptive cell therapy and gene therapy approaches that are just beginning to transform the lives of patients, several novel approaches – including antibody-drug conjugates, immune checkpoint modulators, metabolic immunotherapies, and vaccines – are showing tremendous promise in the pipeline against a broad range of cancers. Today, there are 1,120 medicines and vaccines currently in development for cancer.^{xvii}
- *Heart disease and stroke*: Cardiovascular disease is the leading cause of death in the United States, affecting 92.1 million American adults. There are currently 200 medicines in development for heart disease and stroke. One promising investigational medicine is a non-viral gene therapy that targets a tissue and regeneration pathway that promotes cardiac function, cell survival, and the repair of injured heart tissue in patients with ischemic heart failure.^{xviii}

Today's biopharmaceutical pipeline has tremendous promise and represents a new frontier of research with the potential to transform the lives of patients. In this new era of medicine, science that was once considered unimaginable is now on the verge of producing a complete paradigm shift in the treatment of the most complex and challenging diseases of our time. As the health care market continues to evolve towards value-driven payment and greater patient engagement in health care decision-making, we need to ensure it is sustainable and balances patient access to innovative medicines without sacrificing investment in further treatments and cures.

Many Factors Impact the List Price of Medicines:

The calculations behind drug pricing are complex and can be based on several factors.

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%.^{xix} 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.^{xx}

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. As a result, aggregate rebates, discounts, and other price concessions from biopharmaceutical manufacturers more than doubled^{xxi} in a six-year period – from \$74 billion in 2012 to \$166 billion in 2018 – but co-pays, coinsurance, and deductibles continued to rise.

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 5.5% annually since 2015, while net prices (which take discounts and rebates into account) have grown by just 0.3%.^{xxii}, driven by patent expirations and increased competition from generics. Between 2019 and 2023, IQVIA projects annual net price growth for brand name drugs will be -1 to 2%, highlighting the important role rebates and discounts will continue to play in containing prescription medicine spending growth in the future.

In addition to low price growth, the most recent data from government actuaries and pharmacy benefit managers (PBMs) confirm that retail prescription medicine spending growth has been exceptionally low in both past two years. For example, Express Scripts – the nation’s largest PBM – reported net prescription medicine spending grew just 0.4% in 2018, the lowest level since it began reporting in 1993.^{xxiii} In addition, CMS actuaries reported net retail prescription medicine spending grew just 0.4% 2017, the lowest growth rate since 2012.^{xxiv} Total spending growth for other health care is projected to be 5 times that of prescription medicines through the next decade.^{xxv, xxvi}

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

Patients do not always benefit directly from the rebates and discounts provided by biopharmaceutical companies as they should, in the form of lower cost sharing, resulting in affordability challenges for some. 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.^{xxvii} They use brand competition to obtain discounts from manufacturers and take full advantage of the presence of generics to drive savings. 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,^{xxviii} 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.^{xxix} Additionally, biosimilar competition in the biologics market will increase substantially over time as the market matures.^{xxx} There is no similar type of cost containment for other health care services. However, questions have been raised regarding how much of these negotiated rebates and discounts are making it through the pharmaceutical distribution system. The market dynamics discussed above have resulted in distribution costs accounting for a growing share of what is reported to be prescription drug spending. In 2015, less than half of all net spending on prescription medicines – or about 7% of total health care spending – went to brand biopharmaceutical manufacturers.^{xxxi}

One reason that it seems as if the costs of medicines are going up dramatically is because 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.^{xxxii} Asking sicker patients with high medicine costs to subsidize premiums for healthier enrollees is the opposite of how health insurance is supposed to work.

While robust competition in the market has been successful in constraining net prices, government and industry analysts have observed that supply chain intermediaries may have incentives to favor medicines with high list prices and large rebates,^{xxxiii} 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.

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 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.

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.^{xxxiv} Since 2006, deductibles for patients in employer health plans have increased by 360 percent.^{xxxv} Between 2006 and 2017, patient out-of-pocket spending on coinsurance has increased 92 percent while spending on copays has decreased.^{xxxvi} 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.^{xxxvii} As one recent analysis shows, patients are required to pay 12 percent of overall retail pharmaceutical costs versus only 4 percent of hospital costs – even though medicines can help keep patients out of the hospital.^{xxxviii}

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.^{xxxix} 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.^{xl} Patients with chronic conditions are disproportionately impacted by high out-of-pocket costs.^{xli}

Research shows that rebates paid by biopharmaceutical companies often substantially reduce the list prices of brand medicines.^{xlii} 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.

Hospitals Continue to Markup Medicine Prices

A new analysis^{xliii} from the Moran Company found hospitals continue to charge, on average, five times their cost for medicines, driving up cost sharing and premiums for patients across the country. This study builds on a previous study^{xliv} from 2017. Both studies analyzed 20 medicines and found the amount hospitals receive after negotiations with commercial payers is, on average, almost two and half times what they paid to acquire the medicine.

The 2019 study estimated what these markups and margins mean for hospitals that acquire medicines through the 340B drug discount program, which was designed to ensure access to discounted drugs for vulnerable or uninsured patients. Hospitals that participate in the program are given a significant discount on medicines, but it doesn't appear that all of them are using the money to help patients as was intended by the program, and their own data show they are providing less and less care to needy patients even as they purchase increasing amounts of discounted medicines.^{xlv}

To estimate how much money these 340B hospitals are retaining from the program off each medicine, Moran applied a conservative 340B discount to the medicines in their sample. For example, let's take a medicine with an Average Sales Price (ASP) of \$2,500: 340B hospitals can purchase the medicine from the biopharmaceutical company for an estimated \$1,875, and leverage their market power to receive payment from an insurer of \$6,000 for administering the medicine. As a result, \$4,125 is retained by the hospital, meaning Moran estimates these hospitals receive, on average, 3.2 times what the biopharmaceutical company (that researched, developed and brought the medicine to market) receives in payment for the drug.^{xlvi}

In addition to recent research^{xlvii} showing how hospitals push patients to costlier outpatient settings and highlighting issues with hospital consolidation, this study shines a light on a growing problem in our health care system. Please note that all-payer claims databases do not back out manufacturer rebates from their prescription medicine spending totals, and include the markups taken by hospitals on medicines and a host of other categories. So, reported prescription medicine spending is artificially inflated in those two ways in all-payer claims databases.

International Price Comparisons:

The US has the only truly market-based health care system in the world. In many other countries, governments are the primary or only payer of health care and in effect dictate the prices of medicines as a condition of market access. Biopharmaceutical companies are often forced to accept these prices or face further restrictions on

coverage. Some countries have discriminatory policies or threaten to break patents on valuable new medicines. Practices like these force artificially low prices, delay patient access to new medicines and keep some innovative treatments off the market entirely.

In countries that use government price controls, patients face significant restrictions in accessing new medicines and treatment options. That becomes clear when you compare the availability of new medicines in the United States to other countries. Nearly 90% of new medicines launched from 2011 to 2018 are available in the United States compared to just 50% in France, 46% in Canada, and 36% in Australia – countries that use some form of government price controls.^{xlviii} In addition to having fewer options, patients in these countries often must wait years longer, on average, for medications than patients in the United States.

In America, market competition determines the net price of a medicine, patients have faster access to more medicines than anywhere else in the world and doctors and patients work together to decide which medicine is right for them. Policymakers should keep these facts in mind and work toward the right reforms instead of copying the flawed policies of other governments.

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