STATEMENT OF

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BEFORE THE COMMITTEE

ON FINANCE
UNITED STATES SENATE

CONCERNING

DRUG PRICING IN AMERICA:
A PRESCRIPTION FOR CHANGE, PART II

PRESENTED ON

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I. **Overview**

AstraZeneca appreciates the opportunity to engage with the Committee on the important topic of drug pricing in the United States. We would like to emphasize our commitment to addressing these challenges and the important issues raised by the Committee regarding drug pricing and affordability.

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development and commercialization of prescription medicines, primarily for the treatment of diseases in three main therapy areas: Oncology; Cardiovascular; Renal & Metabolism; and Respiratory. We are also selectively active in the areas of autoimmunity, neuroscience, and infection. We are proud to call Wilmington, Delaware, home to our North American Headquarters. We are equally proud that one of our three global Research & Development ("R&D") headquarters is located in Gaithersburg, Maryland.

We are honored to contribute to improving the lives of millions of patients in the U.S. and across the globe. This statement is focused on four points explaining AstraZeneca's purpose, core values, and vision for the future:

- First, we are a science-led organization, as reflected in our continued investment in R&D and our success in introducing new treatments. Continuing to develop treatments that deliver long-term benefits to patients and the overall health of the U.S. population requires society's commitment to supporting investment in innovation through purchasing our medicines for the duration of patent protection at a responsible price that allows for the recoupment of the investment and risk associated with innovation.

- Second, we believe medicines are part of the solution to controlling healthcare costs. They not only improve patient outcomes and increase quality of life, but also reduce downstream costs by keeping people healthy and out of the hospital. This contribution to reducing overall healthcare costs should be considered when discussing drug pricing.

- Third, we recognize that we are only able to improve the lives of patients if they are able to take our medicines as prescribed. To that end, we are committed to sustaining and improving patient access and affordability.

- Fourth, we recognize that the current state of drug pricing in the U.S. healthcare system is not sustainable and that patients are facing increasingly high out-of-pocket costs. We believe that these issues must be addressed urgently, and we hope to be a constructive partner in finding solutions.

II. **Benefits of Innovation and R&D Funding**

Science is at the core of what we do, and we are focused on being at the forefront of scientific innovation to deliver tomorrow's treatments and cures.

Since 2017, the Food and Drug Administration ("FDA") has approved 18 AstraZeneca products or significant indications, and five of our products have received breakthrough therapy designation. Breakthrough therapy designation is designed specifically for the expedited development and review of drugs for serious or life-threatening conditions, and these designations highlight how critical our work is to patient health in the U.S. For example, our oncology medicine CALQUENCE was granted breakthrough therapy designation for certain patients with mantle cell lymphoma and tezepelumab received such a designation for certain patients with severe asthma.

In order to achieve these results, we reinvest a significant percentage of our revenues in research to identify the next generation of life-changing medicines. Over the past several years, we have worked tirelessly to rebuild our R&D pipeline. We now have approximately 8,900 employees in our R&D organization working at sites across the world. Our financial commitment to R&D has been significant. In 2018 alone, we spent nearly six billion dollars on R&D, or 28% of our total product sales—a commitment to R&D that well exceeds the average spending of our research-based peers.[1] Over the past six years, even as our revenues declined, we continued to make substantial investments in both R&D and acquiring products for our pipeline. In 2018, these investments have only just started to contribute to growth of our company.

These results are possible only if society makes a commitment to support innovation so that treatments can be developed to the benefit of society as a whole for years to come.

The development of new drug therapies requires society to make an up-front investment through purchasing our medicines during the patent protection period at a responsible price we charge, and then at a very substantially reduced price for an indefinite period after patent expiry when generics are introduced. Thus, long-term improvements in healthcare derived from new medicines can only be achieved if society is willing to pay a responsible price for a certain number of years that allows for the recoupment of the investment and risk involved in pharmaceutical innovation. Improvements in patient health and reduction of overall healthcare costs over the long-term are a direct result of this commitment to support innovation.

For example, in the U.S., we have seen incredible progress in reducing cardiovascular disease morbidity and mortality. Between 2000 and 2014, age-adjusted mortality rates for cardiovascular and heart disease declined by approximately 35%; several factors have contributed to this decline, but the development of new medicines, including cholesterol-lowering medicines like statins, has played an important role.[2] To

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[1] Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA Annual Membership Survey (2018). https://www.phrma.org/report/2018-phrma-annual-membership-survey

[2] Sidney S, Quesenberry CP, Jr, Jaffe MG, Sorel M, et al. Recent trends in cardiovascular mortality in the United States and public health goals. *JAMA Cardiol.* 2016;1(5):594-599. doi:10.1001/jamacardio.2016.1326

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take an AstraZeneca example, CRESTOR, a statin, was approved by the FDA in 2003. A study of CRESTOR showed that it reduced cardiovascular mortality and morbidity over the lifetime of the patient compared to the standard of care, resulting in economic value.[3]

It is important to note that there are significant risks involved in developing new therapies. Only approximately 12% of therapies entering clinical study are approved, and the average cost of development approaches $2.6 billion.[4] In 2018, return on R&D investment among larger biopharmaceutical manufacturers fell to 1.9%, its lowest point since 2010.[5] If we are not successful, we lose our investment in the therapy. Although we are proud of our success rate, we know that setbacks are inevitable when pushing the boundaries of science. For example, in 2018, we announced with our partner Lilly the discontinuation of Phase III clinical trials of lanabecestat, an investigational treatment for Alzheimer's disease. Such results are disappointing, but are an integral part of the nature of scientific discovery.

Given the risks involved in developing a medicine, strong intellectual property ("IP") protections and exclusivity for innovator products are a key component to ensuring that manufacturers continue to develop therapies that benefit society as a whole. While they create incentives to innovate, it is important to note that IP protections and exclusivity for innovator therapies do not generally prevent other competitor therapies from entering a given class, allowing robust competition to exist; for example, there are seven different statin molecules approved in the marketplace.

Once these protections expire, generic and biosimilar competitors can enter the market, which further increases competition. Again, taking CRESTOR as example, since 2016 when it lost exclusivity, over 16 generic forms have been approved and are available in the market today, driving prices down very substantially. We strongly support this construct and policy efforts to encourage competition. We describe these proposals in section V of this statement.

Finally, it is also worth noting that a significant portion of our R&D occurs here in the U.S. We invest more than $2.7 billion annually in U.S.-based R&D work, employing approximately 2,700 people in our science units within our R&D centers in Maryland, Massachusetts and California. Our approach to R&D is consistent with our broader and long-standing commitment to U.S. jobs in research and manufacturing. Our largest footprint is in this country, with 12,800 employees throughout the U.S. Additionally, we recently completed a $200 million expansion in our Frederick,

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[3] Ohsfeldt RL, Gandhi SK, Smolen LJ, et al. Cost effectiveness of rosuvastatin in patients at risk of cardiovascular disease based on findings from the JUPITER trial. *J Med Econ.* 2010;13(3):428-37. doi: 10.3111/13696998.2010.499758

[4] DiMasi JA, Grabowski HG, Hansen RA. Innovation in the pharmaceutical industry: new estimates of R&D costs. *J Health Econ.* 2016;47:20-33. doi: 10.1016/j.jhealeco.2016.01.012

[5] Deloitte Centre for Health Solutions. Unlocking R&D Productivity: Measuring the return from pharmaceutical innovation 2018. https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/measuring-return-from-pharmaceutical-innovation.html

Maryland facility where biologics, including FASENRA for certain patients with severe asthma, and our immuno-oncology therapy, IMFINZI, are manufactured. This sustained investment in R&D leads to the creation of high-quality jobs and generates economic value in the U.S.

To summarize, because we have put science and research at the center of our company, we have had more success in our R&D pipeline than ever before, delivering long-term healthcare benefits. This success, however, is only possible if society remains committed to supporting investment in innovation.

III. **Value of Medicines**

The investments we make in researching and developing new therapies cannot occur in a vacuum. We must also ensure that our medicines bring value to patients, payers, and the healthcare system as a whole.

We are only able to stand behind the value of our medicines if that value is carefully and appropriately defined. In the healthcare industry and as part of policymaking, there is frequent reflection on the meaning of "value." We believe value must be assessed holistically and include all costs related to the treatment of a given condition. In particular, we must consider improvements in clinical outcomes and quality of life as well as reduction of hospitalizations and other medical costs.

Additionally, the future savings that prescription medicines can bring to the healthcare system by preventing more costly interventions should not be overlooked as their value is considered. A recent study in *Health Affairs* of total Medicare spending per beneficiary from 1999 to 2012 found that the spending growth rate slowed to just 1.1% per year on average since 2005. The study found that half of the total slowdown was attributable to reduced spending growth on cardiovascular diseases and events, like heart attacks and related conditions. Increased medication use for conditions like hypertension, high cholesterol, and diabetes explained half of that effect. The authors noted that while large, even this impact of medications is likely to be understated.[6]

One of our own therapies—BRILINTA—is an example of a medicine used in the cardiovascular setting that brings value to both patients and the broader healthcare system. This oral antiplatelet therapy is indicated to reduce the rate of cardiovascular death, heart attack, and stroke in patients with acute coronary syndrome ("ACS") or a history of heart attacks. For at least the first 12 months following the diagnosis of ACS, BRILINTA has been shown to be superior to clopidogrel, a generic oral antiplatelet. In addition, in patients with ACS, BRILINTA in combination with aspirin resulted in 21%

[6] Cutler D, Ghosh K, et al., Explaining The Slowdown In Medical Spending Growth Among The Elderly, 1999–2012. *Health Affairs*. February 2019. doi: 10.1377/hlthaff.2018.05372

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reduction in cardiovascular mortality compared to clopidogrel in combination with aspirin.[7]

In addition, BRILINTA in combination with aspirin also resulted in lower medical care costs compared to clopidogrel in combination with aspirin. The lower medical costs are driven primarily by fewer hospital readmissions and cardiovascular revascularization interventions—resulting in medical care cost offsets of approximately $1,000 per patient per year.[8] This represents countless hours of patient time better spent with family and friends than in the hospital.

Another example of the value that medicines can provide relates to the relationship between diabetes and heart failure. In 2015, an estimated 30.2 million adults in the U.S. had diabetes, with the vast majority (90-95%) having type 2 diabetes.[9] Up to 50% of patients with type 2 diabetes may develop heart failure.[10] The prevalence of heart failure in the U.S. is expected to increase from 5.8 million in 2012 to 8.5 million in 2030.[11] The total cost of heart failure, which includes direct and indirect costs, is projected to increase from $31 billion in 2012 to $70 billion in 2030, with the majority of these costs (80%) related to hospitalization.[12]

Our oral type 2 diabetes product FARXIGA is a sodium-glucose cotransporter 2 (SGLT2) inhibitor. This newest class of oral diabetes medication has consistently demonstrated cardiovascular benefits for diabetes patients that are absent in older diabetes treatments, further supporting the importance of biopharmaceutical innovation. A recent cardiovascular outcomes trial demonstrated that FARXIGA significantly reduced the risk for hospitalization for heart failure or cardiovascular death.[13] With initial hospitalizations and readmissions for heart failure in the Medicare population exceeding $10,000 for each event in the U.S., it can be readily observed where these new

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[7] Wallentin L, Becker RC, Budaj A, et al. Ticagrelor versus clopidogrel in patients with acute coronary syndromes. *N Engl J Med.* 2009;361(11):1045-57. doi: 10.1056/NEJMoa0904327.

[8] Data on file. 2134602; AstraZeneca Pharmaceuticals LP.

[9] Centers for Disease Control and Prevention (CDC). National Diabetes Statistics Report, 2017. https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf

[10] American Diabetes Association. CV Disease and risk management: standards of medical care in diabetes – 2019. *Diabetes Care*. 2019;42(Suppl 1);S103-S123. doi: 10.2337/dc19-S010

[11] Heidenreich P, Albert N, Allen L, et al. Forecasting the impact of heart failure in the United States: a policy statement from the American Heart Association. *Circ Heart Fail*. 2013;6:606–619. doi: 10.1161/HHF.0b013e318291329a

[12] *Id.*

[13] Wiviott SD, Raz I, Bonaca MP, et al, for the DECLARE-TIMI 58 Investigators. Dapagliflozin and cardiovascular outcomes in type 2 diabetes [published online ahead of print November 10, 2018]. *N Engl J Med.* 2018. http://dx.doi.org/10.1056/NEJMoa1812389. Accessed November 10, 2018.

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therapies can help further reduce total cost of care in the most at-risk patient populations.[14]

In highly complex conditions, the measure of value and effectiveness can be more multifaceted. In cancer, for example, there are several end-points to measure effectiveness, such as progression-free survival and overall survival. To account for this complexity, cost-effectiveness studies for cancer therapies can measure the value in providing the medication earlier in the course of treatment. An example from our portfolio is IMFINZI—currently the only FDA-approved immunotherapy for the treatment of patients with unresectable stage III non-small cell lung cancer whose cancer has not progressed following platinum-based concurrent chemoradiation therapy. Before IMFINZI, patients in this setting underwent a period of "watch and wait" after chemoradiation,[15] and for up to 89% of these patients their cancer was likely to spread further.[16] Based on the PACIFIC trial, IMFINZI may reduce the risk of death for these patients by nearly a third.[17]

In a recent analysis, use of IMFINZI was found to be cost-effective in comparison to the previous "watch and wait" approach to treatment. This cost-effectiveness analysis, published in the *Journal of the American Medical Association* in December 2018, indicates that although IMFINZI consolidation therapy increased national cancer spending, treating earlier in the course of cancer progression may provide significant value.[18]

For a drug therapy to bring the most value to patients and the healthcare system, it is imperative that the therapy is reaching the right patients at the right point in their treatment journeys. At AstraZeneca, we are focused on improving outcomes for patients on a personalized level by identifying the most appropriate treatments. Approximately 90% of our pipeline now has a precision medicine approach and reflects the broad range of cutting-edge technologies, tissue diagnostics, next-generation sequencing and point of

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[14] Ziaeian B, Heidenreich PA, Xu H, et al. Medicare expenditures by race/ethnicity after hospitalization for heart failure with preserved ejection fraction. *JACC Heart Fail.* 2018;6:388-97. doi: 10.1016/j.jchf.2017.12.007

[15] Postmus PE, Kerr KM, Oudkerk M, et al., Early and locally advanced non-small-cell lung cancer (NSCLC): ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. *Annals of Oncol*. Published online July 1, 2017. doi: 10.1093/annonc/mdx222.

[16] Albain KS, Swann RS, Rusch VW, et al. Radiotherapy plus Chemotherapy with or without Surgical Resection for Stage III Non-Small Cell Lung Cancer. *Lancet.* Published online August 1, 2009. doi: 0.1016/S0140-6736(09)60737-6.

[17] Antonia SJ, Villegas A, Daniel D, et al. Overall survival with durvalumab after chemoradiotherapy in stage III NSCLC. *N Engl J Med.* 2018;379(24):2342-2350. doi: 10.1056/NEJMoa1809697. Epub 2018 Sep 25

[18] Criss SD, Mooradian MJ, Sheehan DF, et al. Cost-effectiveness and Budgetary Consequence Analysis of Durvalumab Consolidation Therapy vs No Consolidation Therapy After Chemoradiotherapy in Stage III Non–Small Cell Lung Cancer in the Context of the U.S. Health Care System. *JAMA Oncol.* Published online December 13, 2018. doi:10.1001/jamaoncol.2018.5449.

care diagnostics we have introduced. By more precisely matching patients with the right medicine, we bring greater value to payers and the healthcare system and help to ensure that patients receive the specific therapy that is most appropriate for their treatment needs.

Finally, the concept of value is a key component in our pricing determinations. AstraZeneca has always taken a thoughtful approach to pricing, and we continue to do so, considering many factors. In addition to our significant R&D investments, we consider clinical value, size of patient population, government/payer coverage requirements, patient affordability, competition and other market conditions. We remain committed to pricing responsibly and making our medicines available and affordable to patients.

IV. **Commitment to Patient Access and Affordability**

Although we are thoughtful in our approach to pricing, we know that patients continue to face challenges at the pharmacy counter. We fully recognize that drug therapies cannot bring value to the healthcare system or to patients unless they can access the medicines they need.

Our commitment to affordable access translates into a number of resources and programs that have helped make our medicines available to patients.

A. AstraZeneca Savings & Affordability Programs

To ensure that patients in the U.S. are aware of our affordability programs, we were the first company to include messages about these programs in all of our U.S. television advertisements. Since 2005, every televised advertisement has reminded viewers: "If you can't afford your medication, AstraZeneca may be able to help."

We stand behind this statement. Forty years ago, we were one of the first manufacturers in our industry to establish a patient assistance program to help low-income patients obtain certain medicines free of charge. Through our "AZ&Me" program, we have provided prescription drug savings to more than four million patients in the U.S. and Puerto Rico between 2008 and 2018.

In addition to AZ&Me, we offer extensive copay savings programs to help eligible, commercially-insured patients reduce copay costs at the pharmacy. These copay savings programs are unfortunately not available to Part D patients and this has created challenges for this population, reducing adherence to important lifesaving or life-improving treatments.

B. Value-Based Agreements

We are also working closely with payers and health systems to explore innovative solutions to improve access and affordability that demonstrate the value our medicines bring to patients and the healthcare system. For several years, AstraZeneca has been exploring these types of solutions through value-based agreements where we are willing to work with healthcare stakeholders to tie payment to patient outcomes.

To date, we have entered into approximately 40 value-based agreements across our therapeutic areas with a variety of payers, making AstraZeneca a leader in the field of value-based agreements. As an example, AstraZeneca agreed with Express Scripts that for IRESSA, an oral treatment for certain types of lung cancer, we will fully reimburse Express Scripts for discontinued use before the third fill, including if discontinuation occurs because patients did not respond to treatment.

While most of these agreements have been focused on securing patient access to our medicines and delivering better patient outcomes, where payers are willing, we are also looking to more directly address patient out-of-pocket affordability through these innovative arrangements.

As an example, last month, we announced the initiation of a value-based agreement for University of Pittsburgh Medical Center ("UPMC") Medicare patients who are prescribed BRILINTA. This value-based contract, which was effective as of January 1, 2019, is groundbreaking in two ways. First, the contract lowers the out-of-pocket costs for a UPMC Medicare Part D patient to approximately $10 for a 30-day supply. Second, what UPMC pays for BRILINTA will vary based on patient outcomes, tying the cost of the drug to its real-world clinical performance.

We are currently exploring another value-based agreement in Medicare Part D. In addition to having a significant outcomes-based component, this arrangement would reduce patient out-of-pocket costs. This type of agreement allows patients to access their medicines at a lower out-of-pocket cost and payers to control their overall healthcare costs through paying for outcomes.

However, there remain significant operational and regulatory hurdles to the broader implementation of value-based agreements. Operational challenges include capturing appropriate data and other capabilities on the part of payers that are needed to successfully execute these arrangements. For example, value-based agreements typically require plans to have systems in place to report measures like adherence and readmissions. While many payers and health systems are evolving to meet the needs of the changing healthcare environment, greater investments need to be made in data capabilities. In addition, policy and regulations must advance to support value-based agreements in becoming a standard approach to reimbursement.

We believe that there are steps the government can take to address these challenges to help encourage the timely adoption of value-based agreements, including in public sector programs like Medicare. These recommendations are described in more detail in section V of this statement. Through the partnership of payers and policymakers, we look forward to a future where implementation of value-based agreements across public and private payers is widespread.

C. Discounts and Rebates

Finally, we negotiate rebates and discounts with payers and pharmacy benefit managers ("PBMs")—including in Medicare Part D—to help ensure that our therapies have the most robust access possible. Without providing these discounts and rebates,

many life-savings medicines would not be placed on plan formularies and therefore would be largely unavailable to the patients who need them most. Our estimates for 2018 show that across our products, our average rebate is nearly 50% of our gross revenues in the U.S. Taking BRILINTA as an example, approximately one third of gross revenue is provided back in rebates. For most of our diabetes therapies, rebates well exceed 50% of gross revenues.

Over the past several years, discounts and rebates for our therapies have increased overall, both in the commercial sector and Part D. In recent years, in our primary care portfolio, which includes the majority of our therapies, we have seen flat to declining net effective prices to AstraZeneca for most of our products. Taking CRESTOR as an example, in the five-year period before it lost exclusivity, even though list price increased, in 2011, CRESTOR's average net effective price earned by AstraZeneca was $2.52 per day (one pill per day). In 2016 when CRESTOR lost exclusivity, the average net effective price was again $2.52.

However, discounts and rebates do not necessarily translate to lower cost-sharing for patients. There are a series of factors that impact a patient's out-of-pocket costs, including individual insurance plan benefit design (copayments, coinsurance, and deductibles), formulary placement, provider access, and assistance programs or savings offers. As a science-led, patient-focused company, the fact that many patients struggle with out-of-pocket costs despite the discount and rebates we provide stands counter to our mission of improving patient health.

V. **The Path Forward: Evolving the Current System**

Despite rapidly increasing rebate amounts, affordability of drug therapies is an increasingly significant public policy and public health issue. We agree that the current system is not sustainable—for patients, payers, and society as a whole—and we are committed to engaging across stakeholders to develop a new paradigm that improves affordability and access for patients while ensuring that manufacturers can continue to develop innovative therapies.

To achieve these goals of improving affordability and supporting innovation, we must progress from a volume-based to a value-based healthcare system. We continue to be forward-leaning in this regard, and we encourage other stakeholders to join us in the effort to deliver and pay for healthcare, including drug therapies, in a more affordable, efficient, and effective way.

An important step is to evolve the current system of paying for and delivering drug therapies to one in which patients more directly benefit from the discounts and rebates we provide. Specifically, we believe that patient cost-sharing should be more aligned to a product's net price as opposed to its list price, as is the case today.

However, as we look ahead to the future, even more must be done to improve patient affordability and to truly build a healthcare system based on the value of therapies provided to patients.

A. Value-Based Agreements Should Be the Future Standard

First, in a future system, the default approach should be that pricing and reimbursement for drug therapies are tied to patient outcomes and the value the particular therapy provides. As such, it is imperative that manufacturers and payers—including Part D plans—engage in value-based agreements similar to the IRESSA and BRILINTA examples referenced previously. Policies to encourage these arrangements and to reduce or eliminate existing challenges will be essential to their long-term success. To that end, AstraZeneca appreciates the support of Senators Warner and Cassidy for value-based agreements, as demonstrated by their requests for input on the Patient Affordability Value and Efficiency ("PAVE") Act. This draft legislation would promote the development of value-based agreements by offering increased flexibility for manufacturers to enter into such arrangements, including with Medicare Part D plans.

In addition to the policies outlined in the PAVE Act, there are other ways that the government could facilitate value-based agreements. For example, the Department of Health and Human Services ("HHS") should consider how its recent proposed rule regarding PBM rebates can be structured to protect existing and future value-based agreements. We appreciate that HHS solicited comments on this topic, and we look forward to sharing our perspective in our written comments to the proposal. In addition, to encourage utilization of agreements that best address the government's goals, we recommend that HHS develop a prioritized list of clinical outcomes measures for manufacturers and payers to consider when developing outcomes-based agreements.

Over the past several years, we have engaged with HHS, and specifically the Center for Medicare and Medicaid Innovation ("CMMI"), to advance specific models involving our therapies in the Medicare program. To date, we have not been able to execute on a model with HHS or CMMI and the feedback we have received is that company-specific models are challenging to implement. We look forward to continued dialogue on these issues, and we hope to work with HHS, CMMI and other stakeholders to develop a scalable framework in which innovative models can be implemented in an appropriate way.

B. All Patients, including Medicare Patients, Should Benefit from Reduced Cost-Sharing

Second, a future system should be designed to ensure that all patients benefit from lower cost-sharing, including those patients taking drug therapies on the Part D specialty tier. A recent study found that rates of prescription abandonment and delayed initiation of oral cancer therapies increase as cost-sharing amounts rise.[19] Such a result reflects the need for a restructuring of the current benefit design for specialty products.

[19] Doshi JA, Li P, Petit AR, et al. Association of Patient Out-of-Pocket Costs With Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents. *J Clin Oncol.* 2018; 36(5): 476-482. doi: 10.1200/JCO.2017.74.5091.

Under one potential approach, a portion of manufacturer discounts could be used to fund a reduction in cost-sharing for patients facing the highest cost-sharing amounts. This could be accomplished by establishing a monthly or annual out-of-pocket cap, which would give patients greater certainty in the total amount of out-of-pocket costs they could face. The cap would provide a safety-net for patients that could be funded by a portion of the discounts provided across all Part D products. Such an approach would help ensure that more patients benefit from the discounts manufacturers provide.

C. Use of Biosimilars Should be Supported

Third, we believe that competition is a key component to reducing costs, and that is why we support expanded use of biosimilars in the U.S. As a global company, we operate in countries, particularly those in the European Union, where biosimilar competition is particularly robust. We support a similarly vigorous biosimilars market in the U.S.

We therefore appreciate the efforts of the FDA to increase the availability of biosimilars in the U.S., including the FDA's development of a Biosimilars Action Plan. We support efforts to streamline and improve the efficiency of the biosimilars approval pathway for the benefit of patients.

We also support reimbursement policies that facilitate the uptake of biosimilars. Such policies include Medicare reimbursement rates that ensure that biosimilars can compete on equal footing with innovator products.

D. Market-Based Competition Should Be Maintained

Finally, it is imperative to maintain market-based competition between manufacturers and between plans. Market-based competition plays an important role in keeping costs down. This is how the lifecycle of innovator therapies works today when competitors enter the market and generic medicines become available over time.

The competitive market in the U.S. also provides patients with access to innovative medicines faster. For example, American patients have access to cancer medicines about two years earlier than patients in other countries, including Germany, France, and the U.K.[20] This timely access to new cancer therapies is correlated with improved survival rates; from 1997 to 2012, rates of cancer mortality fell by 20% in the U.S., compared to a 15% reduction in the U.K.[21] Additionally, nearly 90% of newly launched medicines from 2011 to 2017 were available in the U.S., compared to just two-thirds in the U.K., half in Canada and France, and one-third in Australia; and of 14 new

[20] PhRMA analysis of IMS Consulting Group "Patient Access to Innovative Oncology Medicines Across Developed Markets." June 2016.

[21] World Health Organization (WHO). WHO mortality database. http://www.who.int/healthinfo/mortality_data/en. PhRMA analysis of WHO mortality database, using age-specific death rates.

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diabetes medicines launched over that period, only one was available in France.[22] Given the benefits brought to patients by new antidiabetic agents such as SGLT2 inhibitors (reduction in heart failure and hospitalizations for heart failure), U.S. patients and payers greatly benefit from the earlier introduction of these innovative medicines.

While the current system needs reform, some of the benefits to the current structure are the speed of access and reimbursement of new medicines and the robust nature of the negotiations between manufacturers and PBMs, which in turn creates competition between manufacturers. As the system evolves, it is important that this ability to compete is maintained. Therefore, there must be flexibility to continue to negotiate net price by product and indication, among other factors.

This flexibility is necessary not only to maintain competition, but also to facilitate additional innovations in the way drugs are priced and reimbursed. For example, variable discounts could be used to reduce cost-sharing for patients over time as they remain adherent to their medications. Additionally, we support the concept of indication-based pricing, which recognizes that the value of a drug therapy with more than one indication may vary based on indication. Indication-based pricing would allow greater competition among manufacturers based on the clinical efficacy of their therapies on an indication-by-indication basis. Allowing discounts to vary based on the indication for which a therapy is prescribed will be key to facilitating indication-based pricing.

Finally, we would like to acknowledge that the coverage and reimbursement policies in Medicare Part B have been criticized for not sufficiently encouraging price competition for physician-administered drug therapies. We are supportive of reforms in the Medicare Part B program to address these concerns. Such reforms could include an inflation penalty if a manufacturer's price increase exceeds a certain threshold, as well as steps to ensure that the government and Medicare patients more directly benefit from the discounts and rebates provided in the commercial sector. Similar to the suggestion above on creating a Part D out-of-pocket cap funded by a portion of manufacturer discounts, the savings generated from an inflation penalty and increased competition in Part B could be used to fund an out-of-pocket cap for Medicare Part B patients.

Competition is a fundamental requirement to reducing costs over time, both in Medicare Part B and Part D. Flexibility in the future system will be necessary to maintain competition and to explore additional innovations in the pricing and reimbursement of drug therapies. We must also be willing to work together to improve the efficiency of the Part B program. We look forward to working with policymakers and other stakeholders to shape the future system to accomplish these goals.

VI. **Conclusion**

Although there is no single solution to the challenges we face, we welcome the opportunity to speak with you about ways to evolve our healthcare system. We share

[22] PhRMA analysis of IQVIA Analytics.

your concern that many patients are facing challenges with out-of-pocket costs, and we are committed to working towards solutions that support patient access and affordability while sustaining innovation. AstraZeneca, along with many others in the pharmaceutical industry, is innovating to discover and develop tomorrow's cures and treatments, and we know we need to be a constructive partner to find solutions to ensure that patients benefit from the therapies we develop.