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Improving Drug Pricing Transparency and Lowering Prices for American Consumers

**Before the Committee on Energy and Commerce Subcommittee on Health
United States House of Representatives**

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Chairwoman Eshoo, Ranking Member Burgess, and distinguished members of the Subcommittee, my name is Mark Miller, and I am the Executive Vice President of Health Care at Arnold Ventures. Arnold Ventures is a philanthropy dedicated to addressing some of the most pressing problems in the United States. We invest in sustainable change based on a strong foundation of evidence. We drive public conversation, craft policy, and inspire action through education and advocacy. Until recently, I was privileged to serve the Congress for 15 years as Executive Director of the Medicare Payment Advisory Commission (MedPAC) by providing analyses and policy recommendations. I want to thank you for inviting me to testify today on policies designed to address the unsustainable prescription drug cost burdens to public programs.

Arnold Ventures is dedicated to reforming dysfunctional programs and systems to ensure a better return on investment for the people they serve and those who finance them. To that end, we work to develop an array of evidence and ideas to improve public policy that can drive reform in the areas such as health care, pensions, education, and criminal justice – areas we believe are not serving target populations or taxpayers well. Arnold Ventures is drawn to issues characterized by a lack of evidence, dysfunctional markets, inefficiently run and/or under-resourced government programs, and strong interests protecting the status quo. We strongly believe in markets, but we also believe in evidence-based interventions when markets are failing and competition is lacking. Within health care, we have seen market failures cause stress to patients and their families; to federal and state budgets; to employers; and to taxpayers.

Our objective in health care is to lower cost while maintaining and enhancing access to needed, high-quality care. Across the health care system, we focus on opportunities to achieve more affordable care while securing better health outcomes. We focus on four areas where we see the greatest problems and opportunities. These four areas are 1) reducing hospital and physician prices and costs, 2) rationalizing prescription drug prices and purchasing approaches, 3) identifying and avoiding low-value and/or unsafe care, and 4) improving the care for Americans with complex health conditions and needs.

We know that health care costs are a top issue for Americans. Rising health care spending is squeezing government, business, and household budgets. Nearly half of Americans are concerned that a major health event may bankrupt them, while 77 percent are concerned that the rising cost of health care will significantly damage the US economy.¹ The immediate economic consequences of high health care costs can be staggering. In the last year, Americans borrowed \$88 billion to help pay for health care.² In fact, these costs actively prevent patients from seeking the medical care they need with 65 million adults reporting that they did not seek treatment in the past year due to costs.³ It is not surprising that the most important issue for American voters in 2018 was health care, and within health care, one of voters' highest priorities is lowering prescription drug prices and costs.⁴

With respect to drugs, our ultimate goal is to strike a fair balance between the industry's incentive to innovate and the affordability of medications that improve, extend, and sometimes literally save lives.

We believe the science behind new medications is the best it has ever been. Diseases that in the recent past would be debilitating or life threatening can now be managed through medication. The predicted life expectancy of a child born with cystic fibrosis has risen from 29 years in 1986 to 47 years in 2016.⁵ A 12-week regimen can now cure hepatitis C. Advanced therapies like CAR-T hold the potential to cure cancer in a single treatment, and there is a growing pipeline of gene therapies on the horizon that hold the promise of treating or curing a variety of once-deadly genetic conditions.

However, we have several concerns. First, these treatments are launching at increasingly unsustainable prices that are not justified by their research and development costs. Life-extending cystic fibrosis treatments cost nearly \$300,000 a year.⁶ The cost of curing hepatitis C can be tens of thousands of dollars per treatment.⁷ CAR-T therapy can easily top \$500,000, and several companies have discussed pricing gene therapies above \$2 million dollars per person treated.^{8,9,10} Second, the pipeline is shifting to high priced, specialty drugs, which are expected to comprise nearly half of pharmaceutical industry revenues by 2022.¹¹ Third, given the complexity of these drugs and the dysfunction in our current system, they will often face limited competition, which will keep prices high. These drugs only work if patients can afford to take them and if the cost of these drugs does not crowd out other needed medical care or other necessities such as housing and food.

Arnold Ventures funds research to address high drug prices in a few key areas:

- Identifying the drivers of innovation and developing alternative incentive structures that drive innovation;
- Encouraging competition by reforming our current patent and exclusivity system that grants monopolies to pharmaceutical companies for decades. This includes ending abuses such as pay-for-delay settlements, product hopping, patent thickets, evergreening, and other techniques intended to keep competitors off the market;
- Rethinking the way we pay for drugs to move away from high list prices and price increases and move towards alternative methods of payment including reference pricing, paying on the basis of the clinical value of a drug, and some form of negotiation; and
- Increasing transparency throughout the drug delivery and payment system. This includes ensuring accountability to the public for launch prices and price increases, understanding how money flows from manufacturers to pharmacy benefit managers (PBMs) and supply chain middlemen, and clear reporting of payments by manufacturers to providers and patient groups.

We believe America can remain at the vanguard of medical research and innovation while also ensuring the affordability of the fruits of this research.

Americans Demand Action

The American public believes unequivocally that drug prices are too high. Eight in ten adults feel that the cost of prescription drugs is unreasonable.¹² The same overwhelming majority of adults also believe that drug company profits are a major factor contributing to high prices.¹³ Nearly a third of American adults report not taking a prescription as directed because of cost.¹⁴ Unsurprisingly, there is overwhelming support for strong Congressional action to address the mounting drug-pricing crisis.

Sixty eight percent of Americans, including most Democrats and Republicans, say that lowering prescription drug costs should be the top health care priority for Congress.¹⁵ An overwhelming majority of Americans, both Republicans and Democrats, support aggressive action to lower drug prices including

making it easier for generic drugs to come to market and allowing the government to negotiate prices in Medicare.¹⁶ Voters across party lines and in a variety of Congressional districts have supported government intervention in drug patent monopolies and manufacturing to help speed affordable prescriptions to market.¹⁷

Congress has taken some initial steps to respond to the public's call to action. Congressional committees have held over a dozen hearings and several markups in 2019 focused on drug prices, patent abuses, and the drug supply chain. The Energy and Commerce Committee alone has held 6 of these hearings.¹⁸ Federal legislators have introduced 66 bills to address drug pricing this year from both sides of the aisle. There is legislation addressing new tools like negotiation, importation, and international reference prices that have policy goals that are consistent with voters' demands. In a few instances, these proposals are embraced on a bipartisan basis.

The House of Representatives recently passed the CREATES Act, the Protecting Consumer Access to Generic Drugs Act of 2019, and the BLOCKING Act of 2019, all of which work to bring lower cost generics and biosimilars to market more quickly.

These bills are only a first step, but more work needs to be done to bring immediate relief to taxpayers, employers, and to patients.

The Cost of Doing Nothing

In 2016, the United States spent \$471 billion on prescription drugs.¹⁹ This includes both retail and non-retail drug spending. National Health Expenditures data show that retail drug spending alone grew by over 30 percent over the 2010-2016 period.²⁰ Total drug spending (including non-retail) is expected to rise by nearly a quarter to \$584 billion by 2020.²¹ This expenditure must be taken in the larger context of spending in America. Federal debt held by the American public currently stands at about 78 percent of GDP and is expected to approach 100 percent by 2029.²² Spending on health care is about 18 percent of GDP.²³ Both of these numbers are expected to grow in the near future. In fact, the Congressional Budget Office projects that rising health care costs, along with payments to service the federal debt, are among the largest drivers of increasing federal spending in the future.²⁴ Budget tightening is being felt at the state level as well, and states are being asked to choose between health services and schools, roads, or public safety services.

This spending growth is mirrored in federal and state programs like Medicare and Medicaid. In Medicare Part D, total net spending on prescription drug claims grew from about \$55 billion in 2007 to nearly \$120 billion in 2017.²⁵ From 2007 through 2017, reinsurance payments to Part D plans, which are financed largely by the taxpayer, rose at a rate of nearly 17 percent per year.²⁶ The program's costs to the taxpayer are rising faster than premiums paid into Part D.²⁷

Medicare Part B, which covers physician-administered drugs, experiences similar drug spending growth. Spending on Part B drugs neared \$30 billion in 2016, which is nearly double the amount spent in 2010.²⁸ MedPAC notes that price increases account for two-thirds of the growth of Part B drug spending (excluding vaccines).²⁹ Between 2009 and 2016, spending on drugs in Part B grew 10.7 percent per year while the average payment per drug increased by 6.9 percent per year, which reflects increases in the prices of existing drugs and shifts in the mix of drugs to new, higher priced drugs.³⁰ Together, this is part of the reason why 15 percent of an average Medicare household's total spending is on health care.³¹

Medicaid programs are under pressure from rising drug costs as well. Net spending on retail drugs grew nearly 60 percent over the 2011 to 2017 period.³² In total, the federal government and states spent \$33 billion on drugs in 2017 after rebates.³³ This growth, driven by Medicaid expansion and high cost

therapies like those that treat hepatitis C and cystic fibrosis, puts unnecessary pressure on taxpayers and has outstripped traditional pharmacy cost containment measures.

Ultimately, drug spending is placing an increasing burden on patients, employers, and taxpayers to cover the bill. About one in three Americans chose not to fill a prescription last year because of cost.³⁴ Specialty medications cost, on average, over \$50,000 a year at retail prices, and many people with employer-sponsored health insurance have to pay, on average, 27 percent of this amount, or nearly \$14,000.^{35,36} This is particularly concerning considering that 40 percent of households would find it hard to produce \$400 in an emergency.³⁷

Whether we like to admit it or not, we do ration drugs in our country. If a drug manufacturer with a monopoly chooses to set an excessive price, it forces patients and payers to make difficult tradeoffs. Here are two examples.

- *Insulin.* There are more than 30 million Americans with diabetes.³⁸ Insulin list prices have tripled in the United States over the last decade, while out-of-pocket costs per prescription doubled.³⁹ List prices for insulin seem to be rising in lockstep, which prompted several lawsuits alleging that insulin manufacturers are price-fixing.⁴⁰ These prices require some people with diabetes to ration or skip doses. Researchers at Yale recently found that one-quarter of those studied used less insulin than prescribed due to high out-of-pocket costs.⁴¹ As highlighted in recent press stories, high costs are requiring some people with diabetes to ration, which makes them incredibly ill and, in some cases, causes death.^{42, 43, 44}
- *Hepatitis C Treatments.* Several new products cure hepatitis C. They initially cost nearly \$100,000 per course of treatment. The high price of these regimens and high demand for them led payers to restrict access due to affordability concerns.⁴⁵ Most state Medicaid programs were only making these drugs available to patients whose condition had advanced considerably. Additionally, two-thirds of states required drug testing before they would cover the medication. These limitations on access were inconsistent with clinical recommendations and FDA guidelines. As a result, many people who would have benefitted from these drugs did not gain access.⁴⁶

In 2015, Washington state estimated that even with discounts, treating everyone on Medicaid with hepatitis C would cost three times the state's total pharmacy budget.⁴⁷ In 2017, if Louisiana wanted to treat its entire Medicaid and uninsured populations with hepatitis C, it would necessitate reallocating more than half of the amounts spent on public education, social services, and infrastructure.⁴⁸

Given these issues, it is not surprising that most Americans, their employers, and even the doctors who prescribe treatments believe our prescription drug market is broken. They cannot explain or understand why we pay as much as three times or more for the same drugs than patients in other developed nations.⁴⁹

Research and Development Does Not Explain Drug Prices

A common refrain from the drug industry is that high prices are necessary to drive innovative research and drug development, making drugs is hard and risky and America subsidizes research for the rest of the world. Developing drugs is difficult, expensive, and risky. However, the money U.S.-based drug companies make by charging Americans high prices is 176% greater than what is needed to fund their global R&D.⁵⁰ Many patented products were first discovered through taxpayer-funded NIH research and grants, which contributed to the development of all new molecular entities approved by FDA between

2010 and 2016.⁵¹ Rather than embodying the ideals of competition and choice, the American system, when examined closely, appears to be rife with market failures and perverse incentives.

Manufacturers Block Competition.

Instead of encouraging research into the next generation of cures, firms with drugs approved by the Food and Drug Administration (FDA) are incentivized to hold on to their monopolies as long as possible and deploy as many anticompetitive tactics as possible to ensure generics or biosimilars are not available. The FDA and the United States patent system were designed to create a virtuous cycle: innovator companies are granted certain exclusivities through the FDA and United States Patent and Trademark Office for their work, and when those exclusivities expire, cheaper alternatives like generic drugs or biosimilars become available. Ideally, this would, over time, ensure there is budgetary room for future products, but this is not happening.

Between 2005 and 2015, over 75 percent of drugs associated with new patents were for drugs already on the market.⁵² Of the roughly 100 bestselling drugs, nearly 80 percent obtained an additional patent to extend their monopoly period at least once—nearly 50 percent extended it more than once.⁵³ For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71.⁵⁴ For these same drugs, invoice prices have increased by 68 percent.⁵⁵ Manufacturers also engage in pay-for-delay schemes, in which payment is made to generic firms to not compete for a product. Even in cases where the Federal Trade Commission fines a company for these tactics, the profits made from the delay may outstrip the fine, effectively incentivizing illegal behavior.⁵⁶

Pharmaceutical companies will often point out that, despite invoice and list prices increasing at an alarming rate, the net price paid for drugs has been increasing much more slowly. This begs a further question, why is the gulf between list and net prices widening? The answer may often lie in the pharmaceutical supply chain. PBMs and wholesalers within the supply chain may retain some of the rebates paid off list price. In exchange for these rebates, branded drugs often receive favorable treatment on formularies and are sometimes placed preferentially ahead of generic or biosimilar versions. In the end, patients often pay coinsurance based on the higher list price despite the discounts offered to these other players.⁵⁷

Policy Solutions Must be Comprehensive

It is encouraging that bipartisan support for legislative and regulatory fixes is growing. Doing nothing is a policy decision, and it is a decision that has led to ongoing patent abuse and market dysfunction; an opaque supply chain characterized by spread pricing; higher costs of doing business for employers; increasingly unsustainable public programs; and higher out of pocket expenditures for families. As political momentum builds, it is important that policy solutions be comprehensive and address three broad issues:

1. Patent abuses and anticompetitive behaviors by brand name drug manufacturers.
2. Market distortions that create inefficiencies in the way drugs are purchased.
3. High brand name drug launch prices and unjustified annual price increases.

While the focus of today's hearing is on Medicare and legislative efforts to bring greater transparency to drug pricing, we offer several solutions in this section that go beyond the scope of the hearing, but are critical to address in a legislative package aimed at lowering drug prices. We explore changes to the Medicare program and transparency efforts in depth later in the testimony.

1. Patent Abuses and Anticompetitive Behaviors. The Federal government grants patent and market exclusivity monopolies, which manufacturers constantly fight to extend. As mentioned previously, manufacturers are employing in a variety of anticompetitive tactics to maintain their monopoly. The following are additional changes that could be contemplated as part of a larger package that would encourage greater competition:

- Allowing FDA the authority to import a generic drug when there are fewer than three manufacturers in that drug's class;
- Restricting the orphan drug market exclusivity period to one period for a given drug, or alternatively, allow the market exclusivity period to last only to the point that the patient population exceeds 200,000 for a given drug;
- Removing the interchangeability designation for biosimilars to encourage substitution of lower priced alternatives to biologic medicines. If interchangeability is not removed, the FDA should clarify its scientific approach to the designation;
- Shortening the FDA exclusivity granted to biologics;
- Mitigating product hopping by requiring manufacturers to keep the original formulation of the branded product on the market past the date of generic entry to ensure sufficient market share can move to the generic product;
- Prohibiting citizen petitions filed by competitors that are usually found to be frivolous or, alternatively, fine manufacturers when their citizen's petition is found to be frivolous;
- Reducing Medicare Part B payment for brand drugs from average sales price (ASP) plus 6 percent to ASP minus 33 percent when a manufacturer files a pay-for-delay agreement or takes another anti-competitive action after the primary patent or market exclusivity period expires, whichever date is earliest.⁵⁸

2. Market Distortions. The way drugs are paid for and delivered in the US can have an outsized impact on the prices and availability of drugs to the patients who need them. PBMs are paid in part through rebates negotiated off of list prices, which can incentivize the use of higher cost therapies. Manufacturers also use rebates, in addition to co-pay coupons, and free samples to incentivize the use of higher cost therapies, and manufacturers pay millions of dollars a year to patient groups to advocate on their behalf.

- *Co-Pay Assistance and Direct-to-Consumer (DTC) Advertising.* Co-Pay assistance programs and DTC advertising can steer individuals with insurance to higher cost, brand medications.^{59, 60} Expenses related to DTC advertising and co-pay assistance programs used by individuals with insurance are calculated as business costs that are subtracted from pharmaceutical company revenues and subsequently reduce the company's tax liability. In turn, the federal government is losing corporate tax revenue because of the way these expenses are treated. There are a few options to address this:
 - Require that DTC and direct patient financial assistance to those with comprehensive insurance be a taxable expense.
 - Ban financial assistance in competitive markets. This could either be a ban if a product has a generic or biosimilar competitor or a ban if there are a certain number of products in a class.
- *Transparency.* Manufacturers are not required to disclose their prices, discounts given to intermediaries, or their contributions to patient groups advocating on their behalf. The Committee marked-up and reported H.R. 1781, the Payment Commission Data Act of 2019, which allows MedPAC and MACPAC access to rebate data. This is an important first step to

ensure that all the agencies supporting Congress provide members with complete information to inform the policymaking process.

We go into some detail about expansions to the Sunshine Act and price transparency below. Both are important to informing the government, patients, and taxpayers about the business decisions that affect drug prices, but transparency legislation alone will not be sufficient to lower high drug prices.

3. High Launch Prices and Unjustified Price Increases. As discussed earlier, drugs are launching at higher prices each year, particularly for specialty products, which are becoming a larger percentage of the pipeline and, in turn, drug spending. Below are some policy options to consider that would help lower drug prices for Medicaid and the commercial sector:

- Medicaid Prices
 - Allow states more flexibility in managing their drug benefit while maintaining access to the statutory rebate.
 - Increase the statutory rebate cap, which caps a manufacturer's rebate liability at 100 percent of its price. The cap in current law protects manufacturers from paying more rebate if their prices continue to grow faster than inflation.
 - Include authorized generics in the statutory definition of a "line extension" for purposes of the Medicaid rebate program.
- Commercial Prices
 - Eliminate Medicaid's best price provision to give commercial plans more leeway to negotiate lower prices while increasing the Medicaid statutory rebate to ensure drug prices paid by the Medicaid program do not go up.
- Medicare policy options are addressed in the next section.

Policy Options to Lower Drug Spending and Increase Affordability in Medicare

The remainder of the testimony will focus on potential fixes to the way Medicare Part B and Part D purchase drugs and efforts to increase drug pricing transparency. Consistent with the mission of Arnold Ventures, we offer an array of credible ideas for Congress to consider in crafting a solution to these problems. The status quo represents a series of choices and trade-offs that we believe are unfair to the taxpayer and the patient. Any new policy will also require choices and tradeoffs across patients, taxpayers, PBMs, and manufacturers. These tradeoffs demand careful consideration, but we feel that a balance can be found that more equitably benefits each of these groups.

Medicare Part B

In Medicare Part B, drugs and biologics dispensed by physicians are reimbursed using a buy-and-bill system. Under this structure, physicians are paid for the price of a drug based on its average sales price plus a set percent. Because the set percent paid to the physician is based on the drug's price, it can encourage providers to use higher cost medications in order to bring in higher revenue.⁶¹ The types of drugs used in Part B also complicate matters. These physician-administered products are often high cost, specialty drugs or biologics. The top 11 drugs by spending in Part B in 2017 were biologics representing nearly half of all drug spending in the program.⁶² These drugs typically face very limited competition.

A number of payment reforms could move away from incentivizing the use of high cost drugs and instead encourage the use of the most clinically appropriate product, regardless of price, or the use of lower-cost alternatives.

1. *Reduce or reform the average sales price (ASP) add-on payment for physician-administered drug reimbursement.* This could either be calculated as a lower percentage add on (e.g., from 6 percent to 3 percent) or as a flat add-on fee.
2. *Require manufacturers to pay Medicare a rebate when their ASP growth exceeds an inflation benchmark.* This type of inflation penalty is used in Medicaid to recover excessive price growth. It would reduce both the prices paid for Part B drugs and the associated beneficiary cost sharing.
3. *Require that Medicare use the same billing code for biosimilars and their reference biologic product.* This would force head to head competition between products that would drive down prices.
4. *Allow physicians to form purchasing groups and negotiate their own formularies for physician-administered drugs.* This would mimic some of the cost-containment techniques already used in the Part D benefit and by private plans and would allow groups to leverage purchasing power and market forces to negotiate for lower prices.
5. *Improve ASP data reporting by requiring all manufacturers to report ASP data.*
6. *Reduce the amount Part B pays for new single-source drugs from 106 percent of wholesale acquisition cost to 103 percent.*

Recently, the Administration introduced the International Price Index (IPI) Model, which benchmarks Medicare reimbursement for Part B drugs to an international reference price.⁶³ We believe models that blend international reference prices into the ASP are worth examining. They have a chance to reduce costs for beneficiaries and taxpayers significantly while still ensuring access to critical medications.

Medicare Part D

The Medicare Part D program was designed with financial incentives to encourage plan and beneficiary participation to ensure its success. About 44 million of the 60 million people with Medicare have prescription drug coverage under Medicare Part D, and each beneficiary has, on average, 40 plan offerings.^{64,65}

Restructuring Part D to Improve Competitive Pricing

The financial structure that seemed necessary in 2006 is now creating incentives that waste taxpayer money. Here are a few examples. (1) *The Wall Street Journal* recently reported that plans generated over \$9.1 billion in profit since 2006 by overestimating their expected costs and capitalizing on the federal payment structure of Part D.⁶⁶ (2) Part D is required to cover all drugs in six classes, which undercuts plan ability to negotiate rebates. These drugs comprised about 20 percent of Part D spending in 2015, but only 14 percent of prescriptions.⁶⁷ CMS found that price trends for brand drugs are consistently higher for drugs in protected classes than such drugs in non-protected classes.⁶⁸ (3) The benefit structure encourages plans to prefer high cost drugs to move people into the catastrophic region where taxpayers pay 80 percent of the cost.⁶⁹ As mentioned previously, reinsurance payments (80 percent of which are financed by taxpayers) are growing rapidly. Medicare's reinsurance payments to plans are estimated to be seven times the amount they were in 2006, reaching \$43 billion in 2019.⁷⁰ There are over 3.6 million people in Medicare Part D who had drug spending above the catastrophic coverage threshold. Of the 3.6 million, 1.1 million did not receive a low-income subsidy, which is nearly triple the number of people who did not receive the LIS in 2010 (0.4 million).⁷¹

MedPAC has recommended a set of policies that restructure Medicare Part D to give plans greater financial incentives and stronger tools to manage the benefit.⁷² Both recent Republican and Democratic administrations have proposed similar policies.^{73, 74} Taken together, the following proposals would reduce the amount that taxpayers pay to provide the Part D drug benefit to its 44 million beneficiaries. However, the proposals would also expose some beneficiaries to higher cost sharing. In turn, some consideration could be given to using some of the savings to help people with higher out-of-pocket costs.

Benefit Structure

1. Transition Medicare's individual reinsurance subsidy from 80 percent to 20 percent while maintaining Medicare's overall 74.5 percent subsidy of basic benefits.
2. Exclude manufacturers' discounts in the coverage gap from enrollees' true out-of-pocket spending.
3. Eliminate enrollee cost sharing above the out-of-pocket threshold.
4. Modify copayments for Medicare beneficiaries with incomes at or below 135 percent of the federal poverty level to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes (see detailed discussion below).

Plan Flexibility

5. Provide plans with additional leverage to lower prices paid for drugs by removing at least the antidepressant and immunosuppressant drug classes from protected status and by considering recent administrative proposals that give plans additional tools to manage the six protected classes.⁷⁵ To protect the beneficiary, these policies must be coupled with expeditious, well-functioning exceptions and appeals processes.
6. Streamline the process for formulary changes.
7. Require prescribers to provide supporting justifications with more clinical rigor when applying for exceptions.
8. Permit plan sponsors to use selected tools to manage specialty drug benefits while maintaining appropriate access to needed medications.

Penalize Excessive Price Growth

Drugs are launching at higher prices each year, particularly for specialty products, which are becoming a larger percentage of the pipeline and, in turn, drug spending. Once launched, drug prices continue to escalate year-over-year, while clinical efficacy stays the same. In order to address this issue, manufacturers should be required to pay a rebate to the HHS Secretary for drugs purchased by Medicare Part D if the drug's average manufacturer price rises faster than inflation. Manufacturers are required to pay this type of rebate to the Medicaid program. It is a key reason brand-name drugs are significantly less expensive in Medicaid when compared with Medicare Part D.⁷⁶ The savings generated from this policy could be used to provide greater protections to Part D beneficiaries by lowering the burden of their out-of-pocket costs in some capacity.

Require Deeper Discounts for Drugs Provided to the Elderly and Disabled with Limited Incomes

Prior to the Medicare Part D program, Medicaid provided drug coverage to low income individuals enrolled in both Medicare and Medicaid (dual eligibles). Medicaid requires manufacturers to pay a large statutory rebate that is not required under Part D. In turn, manufacturers saved a lot of money when dual eligibles transitioned from Medicaid into Medicare Part D. An additional way for Congress to contain Part D program costs would be to require manufacturers to pay an additional rebate to the

federal government for brand-name drugs sold to low-income enrollees. The rebate would be tied to the Medicaid statutory rebate, which for brand-name drugs is usually 23.1 percent of the drug's average manufacturer price plus an additional, inflation-based amount. A variant of this idea is to apply the rebate calculation described to a selected set of high cost drugs (e.g., drugs that under normal use would result in the beneficiary exceeding the catastrophic limit) that do not have a competitor or have a brand competitor(s) but prices remain high.

Bringing Rebate and Price Concession Transparency to Part D

In addition to the issues with Part D benefit design and plan flexibility, there are transactions such as rebates, pharmacy fees, and other forms of compensation that occur in the supply chain that pose several issues.

Although rebates put downward pressure on premiums, they give plans incentives to steer beneficiaries to drugs with the highest rebates, which also tend to have high list prices. This leads to higher cost sharing for beneficiaries and could accelerate the rate at which a beneficiary reaches the catastrophic portion of the benefit, where taxpayers pick up 80 percent of the cost.

There are several points for consideration. First, we may need to revisit how Part D's financing structure allocates rebates to the taxpayer versus the plan and fix any misalignments. Second, there are other forms of compensation that may not be shared with the program currently. We should ask whether plans should be permitted to profit from these types of compensations without the taxpayer directly benefiting. Third, if rebates are creating so many perverse incentives we should closely reexamine their role and determine the best way to restructure the system to be more transparent and benefit both the patient and the taxpayer.

Even if the benefit structure is reformed, plans are given more flexibility and rebate incentives are improved, Part D still has a problem. As mentioned earlier, specialty drugs are filling the pipeline and they tend to face little or no competition. Brand-name specialty drugs accounted for just 1 percent of prescriptions and about 30 percent of drug spending after rebates in both Medicare Part D and Medicaid in 2015.⁷⁷ Between 2010 and 2015:⁷⁸

- Spending per Medicare Part D beneficiary who used a brand-name specialty drug tripled, reaching \$33,460 after rebates;
- Overall spending on specialty drugs in Medicare Part D, after rebates, more than tripled, rising from \$8.7 billion to \$32.8 billion; and
- The average net price per prescription of a brand-name specialty drug grew at an average annual rate of 22 percent in Medicare Part D and 12 percent in Medicaid.

In 2017, high cost specialty drugs accounted for nearly a third of the pharmacy industry's prescription dispensing revenues. This is projected to reach 47% in 2022.⁷⁹

Addressing Part D's Limitations

Part D was constructed to rely on PBMs managing the benefit on behalf of taxpayers and beneficiaries. It assumes that the PBMs can effectively use various tools to leverage significant price concessions from manufacturers. However, as discussed, these tools only lower prices when drugs have competition. PBMs cannot do their jobs and extract price concessions from manufacturers of high cost specialty drugs that do not have competition. We need to think through creative solutions to address this issue to ensure the program's fiscal sustainability.

There are two sets of policies that could address this issue:

1. *Reference pricing.* The program could use the following external prices when setting reimbursement rates for certain high cost drugs:
 - a. Prices paid by a subset of foreign countries similar to the idea proposed by the Administration in its Part B demonstration.
 - b. Prices based on the clinical value of the drug to the patient.
 - c. Prices based on independently developed research and development costs for a given therapeutic class.
 - d. Prices paid for similar drugs with competition or other drugs within a similar therapeutic class.

2. *Introducing Negotiation.* Before Medicare covers certain high cost drugs, the Secretary of Health and Human Services and pharmaceutical manufacturers would negotiate a price. We recognize that there are a number of complex design issues that need to be worked through. As mentioned, this would be restricted to a small subset of high cost drugs with limited competition so it is administratively feasible. This concept of program-level negotiation may be foreign to Medicare, but it is important to keep in mind that the Department of Veterans Affairs engages in negotiation for drugs it purchases on behalf of their patients.

You can combine these two ideas and have reference prices built into the negotiation process in order to guide the bids that are offered.

In both of these policies, once there are a sufficient number of competitors on the market, price negotiation would return to Part D's standard negotiation process.

Bringing Beneficiary Accessibility and Price Transparency to the Drug Market

The Committee requested testimony on several legislative initiatives under consideration, which include eliminating generic cost-sharing for low-income Part D beneficiaries and increased transparency.

Eliminating Generic Cost-Sharing for Low-Income Part D Beneficiaries. Part D plans have limited tools available to them to encourage lower cost drug use by individuals enrolled in the Low-Income Subsidy (LIS) program. Currently, most LIS enrollees pay no more than \$3.40 for generic drugs (and brand drugs with generic equivalents) and \$8.50 for brand drugs without generic equivalents.⁸⁰ These co-payment amounts are set in statute and plans have limited flexibility to modify their structure to ensure the use of the most effective, least costly drugs.

Both the CLAY Act and the President's FY 2020 budget would eliminate LIS co-payments on generic drugs and biosimilars for LIS beneficiaries. We think this proposal would greatly improve access and adherence to prescription drugs for some of the most vulnerable Part D beneficiaries. However, the Congressional Budget Office estimated that this proposal would cost the taxpayer more than \$20 billion over 10 years.⁸¹ Given this significant increase in program costs, we would encourage the Subcommittee to consider the following alternative that modifies the LIS co-payment structure in a way that increases utilization of lower cost drugs while also reducing Part D costs.

Both MedPAC and the President's Budget in Fiscal Years 2016 and 2017 proposed reducing the LIS generic co-payment and increasing the brand co-payment amount.⁸² The Secretary would be able to (1) target particular classes where this structure would be most effective and (2) exclude brand drugs from the policy in classes where there are few lower cost generic alternatives. CBO estimated that this proposal would reduce Part D spending by over \$18 billion over 10 years.⁸³ This policy should include

requirements to ensure access to streamlined prior authorization and appeals processes in cases where therapeutic substitution was not clinically appropriate.⁸⁴

Transparency. Many policymakers and researchers point to a lack of transparency in drug pricing decisions and the business models of manufacturers and supply chain actors as a key blind spot for effective drug price legislation. While transparency efforts under consideration would not lead to lower drug prices, Congress should view these efforts as a way to provide better information and context for more comprehensive reform.

- Justification of Large Price Increases. Legislative efforts that would require manufacturers to report certain information in the event of a drug price increase can help taxpayers, patients, and payers understand more clearly why drug prices are increasing at rates well above inflation.

We think legislation that addresses this issue is most effective if it targets drugs that meet a minimum unit price threshold and those drugs experience a price increase that meet a minimum threshold calculated on both a percentage increase and dollar basis (calculated as a rolling average). This will ensure that reporting occurs for products for which a significant price change is most meaningful. Additionally, legislation should require manufacturers report, in a standardized way, the following types of information:

- Manufacturing and production costs;
- Research and development costs, including clinical trials;
- Tax credit amounts associated with research and development;
- Target Product Profiles;
- Marketing costs, including direct to consumer advertising and health care provider detailing.

The Chief Financial Officer of affected manufacturers should be required to sign an attestation form to ensure the information provided to the Secretary is accurate. The Secretary should have flexibility to add any additional data elements deemed necessary and there should be a penalty for manufacturer noncompliance. Non-proprietary summaries of this information should be available to the public.

- Sunshine Act Expansions. The Sunshine Act requires physicians to report to the federal government gifts from pharmaceutical and device companies that are greater than \$100 and has captured about \$33 billion in payments, similar donations made to non-providers are not required to be reported.⁸⁵ Other areas of concern that would benefit from expansions in the Sunshine Act are the distorting effects of manufacturer payments to patient groups and free drug samples given to prescribers and, in turn, to patients.

Patient groups can act as de-facto lobbyists for pharmaceutical companies. Patients testify at congressional hearings, meet with lawmakers, and provide grassroots influence for legislation.^{86,87} It is critical for Congress to know these groups' funding sources to understand potential biases when they advocate for particular policy changes.

Similarly, drug samples influence consumer demand for, and prescribing of higher cost brand medications, essentially acting as direct marketing by pharmaceutical manufacturers.⁸⁸ It was estimated that, in 2012, pharmaceutical companies spent nearly \$6 billion on free samples provided to physicians, making up over 20 percent of total marketing spend in that year.⁸⁹

The STAR Act, which was reported out of the Ways and Means Committee last month, takes an important step by expanding the Sunshine Act to require the disclosure of free drug samples. We

encourage Congress to expand its scope to ensure that all forms of distorting influence be reported publicly so that patients and lawmakers can better understand the scope of this market. At a minimum, this information should be reported to oversight agencies, researchers, payers, and health plans.

Conclusion

We believe that the system can deliver affordable treatments while also encouraging the development of the next generation of treatments. All of the ideas we offered you today involve trade-offs. We stand ready to support your work and your commitment to find the best policy approaches to achieve this important balance. Chairwoman Eshoo, Ranking Member Burgess, and Members of the Subcommittee, thank you for having Arnold Ventures testify on this important subject.

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