

**Mark Miller, PhD
Executive Vice President of Health Care
Arnold Ventures**

**Investing in the U.S. Health System by Lowering Drug Prices,
Reducing Out-of-Pocket Costs, and Improving Medicare Benefits**

**Before the Committee on Ways and Means
United States House of Representatives**

October 17, 2019

Chairman Neal, Ranking Member Brady, and distinguished members of the Committee, 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. Prior to joining Arnold Ventures, I was privileged to serve this Committee, and the Congress as a whole, for 15 years as Executive Director of the Medicare Payment Advisory Commission (MedPAC) by providing nonpartisan analyses and policy recommendations. I want to thank you for inviting me to testify today.

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: 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 prescription 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.

Notwithstanding the exciting potential of pharmaceutical development for promising treatment advances, 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:

- Developing alternative incentive structures that productively and more affordably 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;
- Restructuring public program coverage and payment design to eliminate disincentives for plans to more aggressively secure lower drug prices while ensuring access to medically necessary medications;
- 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 negotiation, reference pricing, and paying on the basis of the clinical value of a drug; 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 greater 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 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.¹⁴ 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.¹⁵ 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.¹⁶

The Cost of Doing Nothing

In 2017, the United States spent \$481 billion on prescription drugs.¹⁷ 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 2010-2017 period.¹⁸ 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 2029.¹⁹ Spending on health care is about 18 percent of GDP.²⁰ 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.²¹ 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 2017.²² From 2007 through 2017, reinsurance payments to Part D plans which (1) occur after a beneficiary reaches his out-of-pocket (OOP) limit and (2) are financed largely by the taxpayer to subsidize plans for high cost beneficiaries, rose at a rate of nearly 17 percent per year.²³ The program's costs to the taxpayer are rising faster than premiums paid into Part D.²⁴

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 2010.²⁵ MedPAC notes that price increases account for two-thirds of the growth of Part B drug spending (excluding vaccines).²⁶ 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.²⁷ Together, this is part of the reason why 15 percent of an average Medicare household's total spending is on health care.²⁸

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.²⁹ In total, the federal government and states spent \$33 billion on drugs in 2017 after rebates.³⁰ 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.³¹ Specialty medications cost, on average, over \$52,000 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.^{32,33} This is particularly concerning considering that 40 percent of households would find it hard

to produce \$400 in an emergency.³⁴ Excessively high priced products combined with growing deductibles and co-pays make affording and accessing needed medications exceedingly difficult.

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.³⁵ Insulin list prices have tripled in the United States over the last decade, while out-of-pocket costs per prescription doubled.³⁶ List prices for insulin seem to be rising in lockstep across manufactures, which prompted several lawsuits alleging that insulin manufacturers are price-fixing.³⁷ 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.³⁸ 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.^{39, 40, 41}
- *Hepatitis C Treatments.* Several 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.⁴² 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.⁴³

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.⁴⁴ 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.⁴⁵

Given these issues, it is not surprising that most Americans, their employers, and the doctors who prescribe treatments believe our prescription drug market is broken. They cannot explain or understand why we pay as much as two to four times or more for the same drugs than patients in other developed nations.⁴⁶ They are also concerned that high drug prices are driving up their premiums or making coverage for other health care services less generous.

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 higher prices than people in other countries is 176% greater than what is needed to fund their global R&D.⁴⁷ Additionally, 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 2016.⁴⁸

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 ensure there is budgetary room over time 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.⁴⁹ 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.⁵⁰ For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71.⁵¹ For these same drugs, invoice prices have increased by 68 percent.⁵² 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.⁵³

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.⁵⁴

Policy Solutions Must be Comprehensive

It is encouraging that bipartisan, bicameral support for legislative and regulatory fixes is growing. Doing nothing is a policy decision, and it is a decision that will continue to allow 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 the taxpayers who finance them; and higher out of pocket expenditures for families. In short, failing to make major reforms has consequences for seniors, people with disabilities, workers, employers and federal and state health care purchasers, and the taxpayers you and they represent.

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.

We will talk through the key features of recent legislation (1) Medicare Part D redesign, (2) Secretarial negotiation, and (3) Medicare inflation penalties below in the context of the broad issue areas identified above. We also offer other solutions that go beyond the scope of the hearing, but are critical to a comprehensive legislative package aimed at lowering drug prices.

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 skillful at converting regulatory pathways into vehicles for monopoly extension.

We applaud the House of Representatives for passing 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. However, we think comprehensive legislation needs to go further and include the following to address the full array of anticompetitive tactics brand pharmaceutical companies employ:

- 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.⁵⁵

2. Market Distortions.

Plan benefit design and actors in the supply chain (specifically manufacturers and PBMs) can distort the market in ways that drive up prescription drug spending and prices.

Part D Benefit Redesign. The current design of the Medicare Part D program encourages market distortions. The financial structure that seemed necessary in 2006 is creating incentives that waste taxpayer money. *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.⁵⁶

Plan sponsors are not liable for much benefit spending in the coverage gap, which encourages plans to prefer high cost drugs to move people into the catastrophic region where taxpayers pay reinsurance payments that cover 80 percent of the cost.⁵⁷ These reinsurance payments are growing rapidly. They are estimated to be seven times the amount they were in 2006, reaching \$43 billion in 2019.⁵⁸ 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, but hit the catastrophic threshold in 2010 (0.4 million).⁵⁹ These high-cost enrollees accounted for nearly 60 percent of all Part D spending in 2017, up from about 40 percent before 2011.⁶⁰

It is abundantly clear that the benefit needs restructuring to ensure that the taxpayer and the patient are not paying more than they should.

Restructuring Medicare Part D to give plans greater financial incentives to manage the benefit is the right direction.⁶¹ H.R. 3 would decrease government reinsurance from 80 percent to 20 percent of spending for all drugs. For brand-name drugs, it would increase plan responsibility from 20 percent to 50 percent and require manufacturers of brand drugs to pay the remaining 30 percent. It also would eliminate the 5% beneficiary cost-sharing in the catastrophic portion of the benefit and increase plan responsibility for generic drugs from 20 percent to 80 percent. The bill also would require brand manufacturers to pay 10 percent of costs before the catastrophic threshold. The Senate Finance Committee, the current administration, and MedPAC have proposed restructuring the Part D benefit.^{62,63,64} These proposals would reduce the amount that taxpayers pay to provide the Part D drug benefit to its 44 million beneficiaries.

H.R. 3 also increases the generosity of the benefit by creating a maximum out-of-pocket limit. Beneficiaries would only have to pay up to \$2000 out-of-pocket for Part D covered drugs in a given year. As noted above, there is no out-of-pocket maximum under current law.

We think it is critical that plans pay significantly more in the catastrophic region than they do now. Sharing those costs with manufacturers is justifiable policy since it is the high prices they set that are driving more and more people into the catastrophic phase of the benefit. However, given the maturity of the Part D program, it is unclear why the taxpayer needs to provide any additional subsidy above the catastrophic threshold. The Medicare Part D program was designed with financial incentives to encourage plan and beneficiary participation to ensure its success. Currently, 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.^{65,66} The robustness of the current market makes it difficult to defend a role for any additional taxpayer subsidies to Part D plans for high cost beneficiaries.

Part D Plan Flexibility to Curb Market Distortion. 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

We encourage the committee to consider providing 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.⁶⁹ Adopting such a reform would simply give Medicare the same tools used by Fortune 500 businesses and the Government Federal Employee Health Benefit Program (FEHBP). To protect the beneficiary, these policies would be coupled with expeditious, well-functioning exceptions and appeals processes.

Supply Chain Market Distortions. PBMs are paid in part through rebates negotiated off list prices, which can incentivize the use of higher cost therapies. Manufacturers also use rebates, in addition to co-pay coupons, and provide free samples to incentivize the use of higher cost therapies.

- *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.^{70, 71} 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 Energy and Commerce 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.
- *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.⁷² 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.

Broad sunshine law provisions should apply to patient groups that have any notable financial relationships with pharmaceutical companies. Patients testify at congressional hearings, meet with lawmakers, and provide grassroots influence for legislation.^{73,74} 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.⁷⁵ 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.⁷⁶ The STAR Act, which was reported out of the Ways and Means Committee, 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.

3. High Launch Prices and Unjustified Price Increases.

High Launch Prices. 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.

Even if the Medicare Part D benefit structure is reformed and plans are given more flexibility, 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.
- The gross price for one of the most frequently used hepatitis C treatments (an antiviral) averaged about \$31,000 per Medicare Part D claim, and many cancer therapies had gross prices that ranged from about \$10,000 to over \$14,000 per claim.⁷⁹ Because of their high prices, even a single claim for drugs in those classes would be sufficient to meet the Medicare Part D out-of-pocket threshold. In 2017, more than 370,000 enrollees filled such a claim, up from just 33,000 in 2010.⁸⁰

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 2022.⁸¹

Part D was constructed to rely on Part D plans managing the benefit on behalf of taxpayers and beneficiaries. It assumes that plans 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 like Secretarial negotiation to address this issue to ensure the program's fiscal sustainability. H.R. 3 is an important step in this process.

Secretarial Negotiation. H.R. 3 would require the Secretary of HHS to negotiate prices for high cost drugs with limited competition. It contains a process for negotiation that both CBO and the CMS actuaries believe would achieve meaningful savings to the Part D program. As such, Arnold Ventures believes this legislation represents a constructive addition to the policy debate.

H.R. 3 would not give the Secretary the option to restrict access to drugs to extract price concessions. Instead, it would require the Secretary to impose penalties on manufacturers if they refuse to negotiate. The policy does not alter Medicare's benefit structure. It lowers prices, which would lead to greater patient adherence to prescription drugs. Once there is a generic or biosimilar drug available, price negotiation would return to Part D's standard negotiation process, when plans have the most leverage to negotiate lower prices. H.R. 3 also has the Secretary prioritize his negotiations on drugs that would generate the most savings, which ensures that federal resources are used efficiently.

International reference prices would be built into the negotiation process in order to guide the bids offered by both parties. This feature is important since negotiation would target drugs with significant pricing power over PBMs and in turn, the Secretary. This is similar in concept to the Medicare Part B International Price Index proposal the President has advocated for and has indicated is releasing soon,⁸² which works to preserve access to drugs while lowering the prices taxpayers and beneficiaries pay for high cost drugs with little competition.

It is understandable that policymakers, the public, and analysts cannot justify why we pay as much as we do in the U.S relative to other countries. There are studies from Johns Hopkins University, the Health and Human Services Office of The Assistant Secretary for Planning and Evaluation (ASPE), and this committee that show that the US pays anywhere from 1.8 times to 4 times more than other industrialized nations.^[i]

Unjustified Price Increases. Between 2006 and 2017, list prices for more than 100 brand-name drugs used for chronic conditions increased cumulatively by 214 percent relative to the inflation rate in the U.S. economy, which was 25 percent over the same period.⁸³ Many Part D beneficiaries pay a share of a drug's list price when they purchase their drugs at the pharmacy. They also pay a share of a drug's list price during the deductible phase of the Part D benefit.

The list price is a price that manufacturers can set at any level. It does not include the rebates and discounts that Part D plans negotiate with manufacturers. These discounts help keep health plan costs and premiums low but do not directly affect the amount many Part D beneficiaries pay for their drugs at the pharmacy counter.

When list prices increase that quickly, so does beneficiary cost-sharing for many drugs in Part D. This impedes access and adherence to needed medications. While this is felt the most in cases where Part D beneficiaries take high-cost specialty drugs, this also affects beneficiaries taking brand drugs that have been on the market for a very long time, like insulin, to which access is critical. Part D cost-sharing for high-cost drugs can be as high as a third of a drug's list price.⁸⁴

In addition to large list price increases, there are considerable net price increases across top selling brand drugs. Many of these price increases are not supported by evidence of additional clinical benefit. A recent report identified 7 drugs with net price increases that were not justified by additional clinical evidence and estimated that these net price increases cost Americans \$5.1 billion in just two years. Humira alone comprised \$1.8 billion of this two-year total.⁸⁵ It is worth noting that two years represents only about a tenth of the time Humira has been on the market.

Medicare Inflation Penalties. H.R. 3 would require manufacturers to pay a rebate to the HHS Secretary for drugs purchased by Medicare Part D and Medicare Part B if the drug's 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.⁸⁶

An inflation penalty still permits a drug company to set any price it wants and increase the price at any time it chooses.⁸⁷ It would not directly interfere in negotiations between Part D plans. They are still free to negotiate with manufacturers for rebates and preferred formulary placement.

The Medicare Part D inflation penalty would slow list price increases over time, which lowers beneficiary out-of-pocket costs. Additionally, commercial payers also would see lower prices under this policy because list prices grow more slowly over time for drugs where the spread between list prices and net prices is small (typically drugs without much if any competition).

Additional Policy Options to Address High Prices. Below are some policy options to consider that would help lower drug prices for Medicare Part B and Medicaid.

Medicare Part B

Medicare Part B pays physicians a set percent of a drug's price, which can encourage providers to use higher cost medications in order to bring in higher revenue.⁸⁸

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 that Medicare use the same billing code for biosimilars and their reference biologic product.* This would force competition between products that would drive down prices.
3. *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.
4. *Improve ASP data reporting by requiring all manufacturers to report ASP data.*
5. *Reduce the amount Part B pays for new single-source drugs from 106 percent of wholesale acquisition cost to 103 percent.*

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.
- Revisit 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.
- Include authorized generics in the statutory definition of a "line extension" for purposes of the Medicaid rebate program.

Conclusion

Mr. Chairman, on behalf of Arnold Ventures, I wish to commend the Committee for holding today's hearing and for remaining committed to addressing the challenge of ever-rising prescription drug costs and the burden it places on all Americans. Advances in science have given us the ability to manage and even cure diseases that had no treatment even a decade ago. Despite this, the American health care system must find a way to balance scientific discovery and innovation with affordability to patients, employers, and taxpayers.

We believe that the system can deliver affordable treatments while also encouraging the development of the next generation of treatments. We understand that all of the policies you are considering involve trade-offs. We stand ready to support your work and your commitment to find the best policy approaches to achieve this important balance. Mr. Chairman, Ranking Member Brady and Members of the Committee, thank you for having me testify on this important subject. I would be happy to answer any of your questions.

¹ <https://news.gallup.com/poll/248081/westhealth-gallup-us-healthcare-cost-crisis.aspx>

² Ibid.

³ Ibid.

⁴ <https://www.kff.org/health-reform/poll-finding/kff-election-tracking-poll-health-care-in-the-2018-midterms/>

⁵ <https://www.cff.org/CF-Community-Blog/Posts/2017/Survival-Trending-Upward-but-What-Does-This-Really-Mean/>

- ⁶ <https://www.statnews.com/pharmalot/2018/05/04/vertex-cystic-fibrosis-drug-prices/>
- ⁷ <https://www.gilead.com/news-and-press/company-statements/authorized-generics-for-hcv>
- ⁸ https://www.washingtonpost.com/national/health-science/staggering-prices-slow-insurers-coverage-of-car-t-cancer-therapy/2018/07/17/ea7f150c-89a1-11e8-9d59-dccc2c0cabcf_story.html?utm_term=.9a31adc7c1b8
- ⁹ <https://www.wsj.com/articles/biotech-proposes-paying-for-pricey-drugs-by-installment-11546952520>
- ¹⁰ <https://www.reuters.com/article/novartis-gene-therapy/novartis-says-sma-gene-therapy-is-cost-effective-at-4-5-mln-per-patient-idUSFWN1XG00D>
- ¹¹ <http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf>
- ¹² <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs>
- ¹³ Ibid.
- ¹⁴ <https://www.kff.org/health-reform/press-release/most-americans-want-congress-to-prioritize-health-care-costs-fewer-cite-medicare-for-all-and-aca-repeal-as-top-priorities/>
- ¹⁵ <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>
- ¹⁶ <https://subscriber.politicopro.com/article/2019/05/poll-swing-districts-support-bold-drug-pricing-moves-3175337>
- ¹⁷ <https://altarum.org/sites/default/files/uploaded-publication-files/Projections%20of%20the%20Prescription%20Drug%20Share%20of%20National%20Health%20Expenditures%20June%202019.pdf>
- ¹⁸ Arnold Ventures' analysis of Centers for Medicare & Medicaid Services, Office of the Actuary National Health Expenditures Data, Table 16, Retail Prescription Drugs Expenditures.
- ¹⁹ <https://www.cbo.gov/system/files?file=2019-01/54918-Outlook.pdf>
- ²⁰ <https://www.healthaffairs.org/doi/10.1377/hlthaff.2018.05085>
- ²¹ <https://www.cbo.gov/system/files?file=115th-congress-2017-2018/reports/53651-outlook.pdf>
- ²² Arnold Ventures' analysis using the Medicare Part D Prescription Drug Event Data and rebate information in the Medicare Trustees Report published June 2018 to derive the 2017 value and an analysis of Table 1.1 in the following CBO publication <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf> for the 2007 value using Medpac's reporting of 24 million Part D enrollees in 2007.
- ²³ http://www.medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0
- ²⁴ http://www.medpac.gov/docs/default-source/reports/mar18_medpac_ch14_sec.pdf; <https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2019/>
- ²⁵ http://www.medpac.gov/docs/default-source/data-book/jun18_databooksec10_sec.pdf?sfvrsn=0
- ²⁶ Ibid.
- ²⁷ http://www.medpac.gov/docs/default-source/congressional-testimony/04_30_2019_medpac_drug_testimony_for_eandc.pdf?sfvrsn=0
- ²⁸ <https://www.kff.org/report-section/the-financial-burden-of-health-care-spending-larger-for-medicare-households-than-for-non-medicare-households-tables/>
- ²⁹ Arnold Ventures' analysis of Centers for Medicare & Medicaid Services, Office of the Actuary National Health Expenditures Data, Table 16, Retail Prescription Drugs Expenditures.
- ³⁰ Ibid.
- ³¹ <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs>
- ³² <http://files.kff.org/attachment/Report-Employer-Health-Benefits-Annual-Survey-2017>
- ³³ <https://www.aarp.org/content/dam/aarp/ppi/2017/11/full-report-trends-in-retail-prices-of-specialty-prescription-drugs-widely-used-by-older-americans.pdf>
- ³⁴ <https://www.federalreserve.gov/publications/2018-economic-well-being-of-us-households-in-2017-dealing-with-unexpected-expenses.htm>
- ³⁵ <https://www.cdc.gov/diabetes/basics/diabetes.html>
- ³⁶ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2717499>
- ³⁷ <https://www.t1international.com/blog/2019/01/20/why-insulin-so-expensive/>
- ³⁸ Ibid.
- ³⁹ <http://nymag.com/intelligencer/2019/01/rising-insulin-costs-are-a-life-or-death-political-crisis.html>
- ⁴⁰ https://www.washingtonpost.com/news/magazine/wp/2019/01/07/feature/insulin-is-a-lifesaving-drug-but-it-has-become-intolerably-expensive-and-the-consequences-can-be-tragic/?utm_term=.b86ee3fbace5
- ⁴¹ <https://khn.org/news/insulins-high-cost-leads-to-deadly-rationing/>
- ⁴² <https://annals.org/aim/fullarticle/2362306/restrictions-medicaid-reimbursement-sofosbuvir-treatment-hepatitis-c-virus-infection-united>
- ⁴³ Ibid.
- ⁴⁴ <https://www.npr.org/sections/health-shots/2015/12/27/460086615/states-deny-pricey-hepatitis-c-drugs-to-most-medicaid-patients>
- ⁴⁵ <https://drugpricinglab.org/tools/louisiana-budget-allocator/>
- ⁴⁶ <https://www.scientificamerican.com/article/how-the-u-s-pays-3-times-more-for-drugs/>
- ⁴⁷ R&D Costs For Pharmaceutical Companies Do Not Explain Elevated US Drug Prices, Health Affairs Blog, March 7, 2017.DOI: 10.1377/hblog20170307.059036
- ⁴⁸ Cleary EG, et al., Contribution of NIH funding to new drug approvals 2010-2016 PNAS.115(10):2329-2334, 2018.
- ⁴⁹ Robin Feldman, May Your Drug Price Be Ever Green, 5 Oxford J. L. and Biosciences 1, 8, 28 (2018) (peer-reviewed), <https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981>.
- ⁵⁰ Ibid.
- ⁵¹ <http://www.i-mak.org/wp-content/uploads/2018/08/I-MAK-Overpatented-Overpriced-Report.pdf>
- ⁵² Ibid.
- ⁵³ See Robin Feldman & Evan Frondorf, Drug Wars: How Big Pharma Raises Prices and Keeps Generics Off the Market (Cambridge 2017).
- ⁵⁴ See Robin Feldman, Drugs, Money, & Secret Handshakes: The Unstoppable Growth of Prescription Drug Prices 20-21, 28 (Cambridge 2019), see also Robin Feldman, Perverse Incentives: Why Everyone Prefers High Drug Prices: Except for Those Who Pay the Bills, Harv. J. On Legis. (forthcoming 2019), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3162432##; Robin Feldman, Why Prescription Drug Costs Have

Skyrocketed: and Why The Government Needs to Take Action, Washington Post (Nov. 26, 2018), https://www.washingtonpost.com/outlook/2018/11/26/why-prescription-drug-prices-have-skyrocketed/?utm_term=.7303b1a3e6cd

⁵⁵ <https://www.hhs.gov/sites/default/files/fy-2020-budget-in-brief.pdf>

⁵⁶ <https://www.wsj.com/articles/the-9-billion-upcharge-how-insurers-kept-extra-cash-from-medicare-11546617082>

⁵⁷ <http://www.medpac.gov/-blog-/factors-increasing-part-d-spending-for-catastrophic-benefits/2017/06/08/factors-increasing-part-d-spending-for-catastrophic-benefits>

⁵⁸ <https://www.kff.org/medicare/fact-sheet/an-overview-of-the-medicare-part-d-prescription-drug-benefit/>

⁵⁹ http://www.medpac.gov/docs/default-source/default-document-library/status-report-on-part-d_jan-2019.pdf?sfvrsn=0

⁶⁰ https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/MedPAC_Testimony_for_EandC_04_30_2019.pdf

⁶¹ <http://www.medpac.gov/docs/default-source/reports/chapter-6-improving-medicare-part-d-june-2016-report-.pdf>

⁶² <https://www.finance.senate.gov/imo/media/doc/PDPRA%20Committee%20Report%20092519%20FINAL.pdf>

⁶³ Table S-6 <https://www.whitehouse.gov/wp-content/uploads/2018/02/budget-fy2019.pdf>

⁶⁴ http://www.medpac.gov/docs/default-source/reports/jun19_ch2_medpac_reporttocongress_sec.pdf?sfvrsn=0

⁶⁵ http://www.medpac.gov/docs/default-source/default-document-library/status-report-on-part-d_jan-2019.pdf?sfvrsn=0

⁶⁶ <https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-prescription-drug-plans-in-2018/>

⁶⁷ <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2018/03/policy-proposal-revising-medicare-protected-classes-policy>

⁶⁸ <https://s3.amazonaws.com/public-inspection.federalregister.gov/2018-25945.pdf>

⁶⁹ http://www.medpac.gov/docs/default-source/comment-letters/01162019_partd_4180_p_medpac_comment-letter_v2_sec.pdf?sfvrsn=0

⁷⁰ Leemore Dafny & Christopher Ody & Matt Schmitt, 2017. "When Discounts Raise Costs: The Effect of Copay Coupons on Generic Utilization," *American Economic Journal: Economic Policy*, vol 9(2), pages 91-123.

⁷¹ <https://www.kff.org/wp-content/uploads/2003/06/6084-impact-of-direct-to-consumer-advertising-on-prescription-drug-spending-summary-of-findings.pdf>

⁷² <https://khn.org/news/patient-advocacy-groups-take-in-millions-from-drugmakers-is-there-a-payback/>

⁷³ Ibid.

⁷⁴ <https://khn.org/news/drugmakers-help-turn-patients-with-rare-diseases-into-d-c-lobbyists/>

⁷⁵ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4274368/>

⁷⁶ <https://www.pewtrusts.org/en/research-and-analysis/fact-sheets/2013/11/11/persuading-the-prescribers-pharmaceutical-industry-marketing-and-its-influence-on-physicians-and-patients>

⁷⁷ <https://www.cbo.gov/system/files/2019-03/55041-presentation.pdf>

⁷⁸ Ibid.

⁷⁹ https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/MedPAC_Testimony_for_EandC_04_30_2019.pdf

⁸⁰ Ibid.

⁸¹ <http://drugchannelsinstitute.com/files/State-of-Specialty-Pharmacy-2018-Fein-Asembia.pdf>

⁸² <https://www.reginfo.gov/public/jsp/EO/eoDashboard.myjsp>

⁸³ https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/U.S.%20vs.%20International%20Prescription%20Drug%20Prices_0.pdf;
<https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf>;
<https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05207>

⁸⁴ <https://www.aarp.org/content/dam/aarp/ppi/2018/09/trends-in-retail-prices-of-brand-name-prescription-drugs-year-end-update.pdf>

⁸⁵ https://icer-review.org/wp-content/uploads/2019/01/ICER_UPI_Final_Report_and_Assessment_100819_Final.pdf

⁸⁶ <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/reports/45552-PartD.pdf>

⁸⁷ <https://www.healthaffairs.org/doi/10.1377/hblog20190715.557473/full/>

⁸⁸ <https://www.cms.gov/sites/drupal/files/2018-10/10-25-2018%20CMS-5528-ANPRM.PDF>