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Drug Pricing in America: A Prescription for Change, Part I

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United States Senate**

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Chairman Grassley, Ranking Member Wyden, and distinguished members of the Committee my name is Mark Miller and I am the Executive Vice President of Health Care at the Laura and John Arnold Foundation. Until recently, 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 analyses and delivery and payment recommendations. It is a pleasure to be back. I want to thank you for inviting me to testify today on policies designed to address the unsustainable prescription drug cost burdens on the Medicare and Medicaid programs, the populations these programs serve, and the taxpayers who finance them.

The Arnold Foundation 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 of health care, pensions, education, and criminal justice – areas we believe are not serving target populations or taxpayers well. The Arnold Foundation is drawn to issues characterized by a lack of evidence; dysfunctional markets; inefficiently run and/or under-resourced government programs; and by strong interests excessively driven to protect the status quo. We strongly believe in markets, but we also believe in evidence-based intervention when markets are failing and competition is lacking. Within health care, we have seen these market failures cause stress to patients and their families, to federal and state governments, and to employers and taxpayers.

Our objective in health care is to lower cost growth 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/or costs, 2) rationalizing 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 the issue of health care is top of mind to Americans. Rising health spending in general is squeezing government, business, and household budgets. In fact, the most important issue for American voters in 2018 was health care, and within health care, one of voters' biggest priorities is lowering prescription drug prices and costs.¹ 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 saves 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 survival of a child born with cystic fibrosis has risen from 29 years in 1986 to 47 years in 2016.² 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.³ The cost of curing hepatitis C can be tens of thousands of dollars per treatment.⁴ CAR-T therapy can easily top \$500,000 and several companies have discussed pricing gene therapies above \$2 million dollars.^{5,6,7} Second, the pipeline is shifting to high priced, specialty drugs, which are expected to comprise nearly half of pharmacy industry revenues by 2022.⁸ 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.

The Arnold Foundation 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 spread pricing and move towards alternative methods of payment including reference pricing, 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 the affordability of the fruits of this research.

The Broken American Pharmaceutical Market

In 2016, the United States spent \$471 billion on prescription drugs.⁹ That number is expected to rise by nearly a quarter to \$584 billion by 2020.¹⁰ This expenditure must be taken in the larger context of spending in America. Federal debt held by the American public currently stands at about 77 percent of GDP and is expected to approach 100 percent by 2028.¹¹ Spending on health care is about 18 percent of GDP.¹² 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.¹³ 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 drugs was over \$100 billion in 2016.¹⁴ From 2007 through 2016, reinsurance payments to Part D plans, which are financed largely by the taxpayer, rose at a rate of 17.7 percent per year.¹⁵ The program's costs to the taxpayer are rising faster than premiums paid into Part D.¹⁶

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 2010.¹⁷ MedPAC notes that price is the largest factor contributing to the growth of Part B drug spending.¹⁸

Together, this is part of the reason that an average Medicare household will spend nearly 15 percent of their total spending on health care.¹⁹

Medicaid programs are under pressure from rising drug costs as well. Spending on drugs grew nearly 50 percent over the 2011 to 2017 period. In total, the federal government and states spent about \$30 billion on drugs in 2017 after rebates.²⁰ 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 and taxpayers to cover the bill. About one in four Americans chose not to fill a prescription last year because of cost.²¹ Specialty medications cost, on average, over \$50,000 a year at retail prices and many people with employer sponsored insurance have to pay on average 27 percent of this amount, or nearly \$14,000.^{22 23} This is particularly concerning considering that 40 percent of households would find it hard to produce \$400 in an emergency.²⁴

Government Granted Monopolies Drive-Up Prices

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.²⁵

The Level of Research and Development Investments Do Not Explain High Prices.

A common refrain from the drug industry is that high prices are necessary to drive innovative research and drug development and that making drugs is hard and risky and America subsidizes research for the rest of the world. In fact, revenues generated just from sales in America would fund 176 percent of the global pharmaceutical research and development budgets for these companies.²⁶ Between 2013 and 2017, the five largest US-based drug companies spent substantially more on marketing and administrative costs than on research and development.²⁷ 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 Engage in Creative Ways to 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 that 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.²⁸ 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.²⁹ For the 12 top selling drugs in the United States, manufacturers filed, on average, 125 patent applications and were granted 71.³⁰ For these same drugs, invoice prices have increased by 68 percent.³¹ Manufacturers also engage in pay-for-delay schemes, in which payment is made to generic firms to not compete with 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.³²

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. The rebates paid off list price may end up with the PBMs and wholesalers within the supply chain. In exchange for these rebates, branded drugs are often given 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.

Policy Options to Lower Drug Spending and Increase Affordability

It is encouraging that bipartisan support for legislative and regulatory fixes is growing. As evidenced by this hearing, Congress has heard the concerns of American families, businesses, and taxpayers and is interested in finding policy solutions that will balance innovation and affordability. Doing nothing is a policy decision, and it is a decision that we know will lead 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.

And while we recognize that the patent abuses and other anticompetitive behaviors mentioned above are beyond this committee's jurisdiction, they must be addressed in any comprehensive piece of legislation. If they are not, public programs like Medicare and Medicaid will continue to face higher drug prices and expenditures.

During today's hearing, this testimony will largely focus on potential fixes to Medicare and Medicaid. Consistent with the mission of The Arnold Foundation, 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 D

The Medicare Part D program was designed with financial incentives to encourage plan and beneficiary participation to ensure its success. We now have a very robust program. 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.^{33,34}

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.³⁵ (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.³⁶ (3) Experts believe 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.³⁷ As mentioned previously, reinsurance payments 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 2019.³⁸ 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. That number is more than double what it was in 2010.³⁹

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.⁴⁰ Both recent republican and democratic administrations have proposed similar policies.^{41, 42} 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 poverty to encourage the use of generic drugs, preferred multisource drugs, or biosimilars when available in selected therapeutic classes.

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.⁴³ 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.

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, may we 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 be asking whether plans should be permitted to profit from them without the taxpayer directly benefiting. Third, if rebates are creating so many perverse incentives in the program, maybe we should consider moving the entire Part D benefit to one that is paid using claims plus a flat fee. This, perhaps, would be the best way to realign incentives in the program to encourage use of the most appropriate and lowest cost drugs.

Even if the benefit structure were reformed, plans were given more flexibility, and rebate incentives were 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. The average net price per prescription of a brand-name specialty drug in Medicare Part D grew at an average annual rate of 22 percent from 2010 to 2015.⁴⁴ While less than 1 percent of all Part D claims were for specialty drugs in 2017, they comprised a quarter of Part D spending, up from 6 percent in 2007.⁴⁵

Part D is not well-equipped to address these types of drugs, in part because negotiations are disaggregated across plan sponsors. This disaggregation makes negotiating prices for high cost drugs with limited competition less efficient than if the program were able to negotiate on behalf of all beneficiaries. 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. *Negotiation with Binding Arbitration.* Before Medicare covers certain high cost drugs, the Secretary of Health and Human Services and pharmaceutical manufacturers would negotiate a price. If the negotiations fail, a neutral arbitrator would set the price of a drug once presented with a full set of information from which to make the pricing decision. In order to drive more reasonable bids, the arbitration would be highly structured such as those used in baseball to negotiate a player's salary. The arbitrator would have to pick one of the bids.

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 drugs with limited competition so it is administratively feasible. The Secretary would have to appoint or create a neutral arbitrator with drug market expertise (e.g. experts associated with the American Arbitration Association). Additionally, the legal issues of having a third party present a decision to the Secretary would have to be addressed. This concept of program-level negotiation may be foreign, but it is important to keep in mind that the Department of Veterans Affairs engages in negotiation for drugs they purchase on behalf of their patients.

You can combine these two ideas and have reference prices built into the negotiation and binding arbitration 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.

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 plus a set percent, which can encourage providers to use higher cost medications and thus bring in higher revenue.⁴⁶ The types of

drugs used in Part B can also complicate matters. These physician-administered products are often high cost, specialty drugs or biologics. Of the top 10 drugs by spending in Part B in 2016, nine were high cost biologics, which typically face limited competition.⁴⁷

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 and inflation benchmark.* This type of inflation penalty is used to control price growth in Medicaid and 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 be similar to the way generic small molecule drugs are treated. Currently, biosimilars are reimbursed at their own ASP plus a percentage of the reference biologic's ASP. This provides no difference in margin for the administering provider and a weak incentive to use a biosimilar over the higher priced biologic.
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 through private plans and would allow groups to leverage purchasing power and market forces to negotiate for lower prices.

Recently, the Administration introduced the International Price Index (IPI) Model, which benchmarks Medicare reimbursement for Part B drugs to an international reference price.⁴⁸ We believe models like the IPI are worth examining. They have a chance to reduce costs for beneficiaries and taxpayers significantly while still ensuring access to critical medications.

Medicaid

The Medicaid rebate program is very successful at driving down average prices paid by the program relative to other payers. However, states are still struggling to afford new, high cost specialty drugs, where the rebate is less effective in lowering prices. Additionally, since states are essentially required to cover all drugs, they are not getting as good a price as they could if they had additional flexibility.

States are working with the Administration to address this issue creatively. Louisiana recently received approval from CMS to operationalize a “Netflix” subscription model to purchase hepatitis C medications and New York instituted a Medicaid drug spending cap.^{49, 50} However, it is clear that more needs to be done both administratively and legislatively to provide states with additional flexibility to rein in spending.

1. *Provide States Additional Flexibility to Manage the Drug Benefit.* Currently, states do not have as many tools as the private sector to manage the Medicaid drug benefit. If a manufacturer participates in the Medicaid rebate program, a state must cover all of its drugs. States are permitted to use some utilization management tools like prior authorization and quantity limits. If states were given additional flexibility to exclude from coverage certain drugs, while maintaining access to the statutory rebate, states would be able to lower drug spending. This legislative change would ensure that states like Massachusetts and Arizona could pursue the more flexible benefit designs they proposed to CMS.^{51, 52} Obviously, any changes like this would have to be accompanied by a well-designed, rapid appeals process and access to off-formulary drugs when clinically indicated.

2. *Address Misclassified Drugs.* Provide the Centers for Medicare and Medicaid Services the authority to ensure that manufacturers are appropriately classifying their drugs as brands or generics to ensure payment of the appropriate rebate amount to the Medicaid program.
3. *Increase the Statutory Cap on the Brand Rebate.* A unique feature of the Medicaid rebate program is that it has an inflation component. A manufacturer's rebate liability grows if it increases its average manufacturer price (AMP) more than inflation. This inflation-based rebate comprises over half of the average rebate owed on brand drugs.⁵³ The rest comes from the basic rebate, which for most drugs is 23.1 percent of a drug's AMP or the best price given to certain other payers. Under current law, the total rebate amount owed to Medicaid on a brand drug is capped at 100 percent of its AMP. One important scenario is that once a drug's rebate reaches the cap, a manufacturer can continue to raise its AMP without paying additional rebate dollars to Medicaid. If the rebate cap were increased, states and the federal government would receive a larger rebate because of this price increase, making the penalty more reflective of excessive price growth. While this policy would generate savings to the Medicaid program, we recognize that it creates a scenario where some manufacturers would be paying Medicaid to cover their drugs. The cap could be raised by an incremental amount (e.g. 105 percent of AMP) to dampen the effect on manufacturers.
4. *Remove the Statutory Requirement that Manufacturers Blend the AMP of a Brand Drug with its Authorized Generic.* Under current law, the calculation of AMP requires a manufacturer to average the price of its authorized generic product with its branded product. Because the authorized generic is typically much lower in price than its branded counterpart is, this lowers the AMP off which the brand rebate is calculated. MACPAC proposed changing the calculation to exclude the authorized generic price from the calculation of a brand drug's AMP. This would lower the prices states and the federal government pay for certain brand-name drugs in the Medicaid program.⁵⁴

Conclusion

Mr. Chairman, on behalf of The Arnold Foundation, I wish to sincerely commend the Committee for its leadership in 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 properly 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. 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. Mr. Chairman, Ranking Member Wyden 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.

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