Testimony

Testimony on The Lower Drug Costs Now Act (H.R. 3)

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Chairwoman Wilson, Ranking Member Walberg, and members of the committee, thank you for the opportunity to testify before you today regarding The Lower Drug Costs Now Act (H.R. 3) and drug costs broadly. I hope to make three basic points.

- Government negotiation of drug prices, as outlined in H.R. 3, is not in any real sense a negotiation. It amounts to federal price setting and would be a notable deviation from how the federal government has traditionally engaged with markets and private companies.
- Proposals to tie drug prices in the United States to those of other countries are price setting by another name. Importing prices from other countries determined by their own government intervention in the market is in effect importing those countries' price-setting decisions—and potentially those countries' access issues as well.
- In the face of rising demand, the only way to reduce prices without harming innovation or access to treatments is to increase supply and heighten competition. There are actions policymakers can take, and in some cases are taking, to incentivize lower prices and more competition. Policymakers should be cautious in this undertaking, however, as many proposals could do more harm than good.

Let me discuss each of these in turn.

Government Negotiation of Drug Prices

Title I of H.R. 3 would require the Secretary of Health and Human Services (HHS) to enter into a binding negotiation process with the manufacturers of at least 25 branded drugs each year—based on various criteria that I will discuss below—regarding the maximum price Medicare or any third party payer in the United States can be charged for that drug. The premise is regularly repeated: Drugs, particularly those provided through the Medicare Program including the Prescription Drug Program (Part D), are not subject to any competitive pressures; rather, prices are dictated by manufactures who can demand whatever they desire. But this premise is not an accurate depiction of the reality.

Competition and Negotiation in Part D Under Current Law

Direct negotiation by the Secretary of HHS is indeed expressly forbidden in the Part D statute, a fact that certainly contributes to some confusion over this issue. Yet the program nevertheless sees aggressive negotiation over the prices of medications between Part D plan sponsors and drug manufacturers. This competitive process is the key factor in the program's success to date. Today, Part D beneficiaries have access to 27 different plans, on average, enabling individuals to choose a plan that is tailored to their needs.[i] Because there are a number of plan options for beneficiaries, individual plans have the ability to use preferential tiering strategies to negotiate discounts for specific drugs. If a beneficiary requires or desires a specific medication that is not on the preferred formulary (or covered at all) for one plan, they can choose to sign up for a different plan that provides the medication at a more desirable price.

If the government, however, were to seek to negotiate the prices of specific drugs, the system would break down. Plans have leverage to drive discounts because they can restrict or deny access to specific medications or offer the medication in ways that make it more desirable to their beneficiaries. For the federal government to undertake this kind of negotiation, there would need to be a single federal formulary. In other words, the Secretary would have to be willing to say no to many treatments on behalf of all beneficiaries in order to drive discounts system-wide. Beneficiaries' choices would drop from 27 plans to 1. Further, beneficiaries would no longer be able to shop for the plan that is best for them; rather, they would have to simply hope the government was able to negotiate a good deal for the drug(s) they need. Policymakers and the American public have long been reticent to make that trade off. The Congressional Budget Office (CBO) has repeatedly held that in absence of a willingness to deny coverage for specific medications, the Secretary would not have the leverage necessary to drive any savings to the Part D program.[ii] In short, given these constraints, direct negotiation of drug prices by the secretary would not work.

In contrast, the design of Part D has worked incredibly well. As demonstrated in the following infographic, total program expenditures came in far lower than initial CBO projections. Part D's 10-year cost (starting in 2006) was projected in 2004 to be $957.3 billion, after the Medicare Modernization Act was passed but before the program started. By 2011, the combination of five years of actual data and five years of projections totaled $499.4 billion, for a cost under-run of $457.9 billion, or about 48 percent. The last CBO forecast for 2012 Part D spending made prior to implementation was in 2005, and the projected 2012 spending in that year was $126.8 billion. After the bids came in for 2006, the 2012 forecast was reduced to $110.2 billion. In all but one of the next six years, the forecast for 2012 was reduced further. The actual amount was $55.0 billion – about 57 percent lower than the original pre-implementation forecast.[iii]

It is not uncommon for critics of the program to cite the large number of name-brand drugs that came off patent during the early years of the program—the so-called patent cliff—and the ensuing flood of generic medications that entered the market as the reason the initial estimate was so far off the mark. CBO was not caught flat-footed by this development, however, as American Action Forum (AAF) President, and then-CBO Director, Douglas Holtz-Eakin has recounted many times. CBO carefully studied the coming deluge of generic treatments and accounted for that development in their scoring of the program. What they failed to anticipate was how effectively the competitive nature of Part D's negotiations would drive generic uptake.

None of this is to suggest that Part D is not in need of reforms. As AAF experts have previously written, Medicare Part D reinsurance expenditures have grown rapidly for the federal government in recent years. This growth has been driven by an increase in both the number of beneficiaries reaching catastrophic coverage and the share of costs that each of them incurs in the catastrophic phase. This rapid growth has caused reinsurance expenditures to increase from less than one-third of the federal government's subsidy of the Part D program in 2007 to more than two-thirds of the subsidy in 2016. Increasing drug prices are one driver of this increase, but policies and perverse financial incentives affecting the benefit design and insurers' formulary decisions are also to blame. One way to realign incentives is a restructuring of the program's benefit design.

In 2018 AAF proposed to increase insurer liability in the catastrophic phase to roughly 70 percent while simultaneously reducing the government's liability to 20 percent. Then move the drug manufacturer rebate program from the coverage gap to the catastrophic phase to cover the remaining costs. These changes will significantly increase the incentive for both insurers and drug manufacturers to control costs. Further, AAF proposed providing beneficiaries with true financial protection by imposing an out-of-pocket cap. Plan sponsors

and beneficiaries would also benefit from a simplified benefit structure, since the coverage gap would be eliminated and beneficiary co-insurance will be held steady at 25 percent above the deductible until reaching the catastrophic threshold. Such reforms should encourage behavioral changes that reduce overall program costs for all stakeholders.[iv] Variations of this proposal have been included in both the Senate Finance Committee's drug pricing package and H.R. 3, though significant differences exist between the specifics of the three versions.

Critique of Government Negotiation as Proposed in H.R. 3

H.R. 3 seeks to bypass the problems with government negotiation detailed above by empowering the Secretary to negotiate on behalf of all third-party payers for a Maximum Fair Price (MFP), below which Part D Plan sponsors and other payers in the group and individual markets could presumably still negotiate better rates. In order to give the Secretary leverage in these negotiations, without creating a national formulary, the legislation proposes to enact draconian penalties—including a tax of up to 95 percent of the annual gross sales of a product when a manufacturer refuses to enter into negotiation with the Secretary. Under the proposal, the Secretary would choose a minimum of 25 drugs annually, from a list of 250 drugs that are among the 125 highest cost drugs in Part D or Part B and either lack competition as defined in the legislation or are insulin products. As a starting point for the negotiation, the Secretary would establish a ceiling price of 120 percent of the volume-weighted average price of the drug in Australia, Canada, France, Germany, Japan, and the United Kingdom, or the Average International Market (AIM) price. Once the negotiations conclude and the new MFP is established, the manufacturer would be required to offer that price to all payers, including private insurers in the group and individual market. In other words, the federal government would set the price nationwide for all payers. Manufacturers would be prohibited from increasing their price above the rate of inflation. Additionally, payers could seek additional price concessions—which could be particularly important in the commercial market where some plans may well have negotiated lower rates for specific drugs than the ultimate MFP—though it is unclear what incentives manufacturers would have to go below the MFP. Finally, if a manufacturer were to charge more than the MFP they would face civil penalties of 10 times the difference in the price charged versus the MFP.

Three things seem worth noting. First, the rhetoric of a voluntary-bilateral process seems facetious when any manufacturer who declines to participate in the voluntary process is subject to the aforementioned 95 percent tax on gross receipts. Additionally, the process of reaching an agreement on an MFP cannot truly be said to be a negotiation when the manufacturer is required to reach an agreement with the Secretary or else be deemed not

to have negotiated in good faith—and once again face the tax penalty. Using rhetoric like "voluntary" or "negotiation" is not uncommon in policy debates, but proponents of these policies should be forthright about what it is they are advocating for. The process outlined in this legislation appears to be neither voluntary nor a negotiation.

Second, the definition of a product lacking competition is incomplete. Under H.R. 3, a drug is said to lack competition if it is a brand-name drug and does not have a generic or biosimilar competitor. While that phrasing may sound reasonable, it paints an incomplete picture of competition in the drug market. Take the example of Sovaldi, Gilead's Hepatitis-C cure that was originally launched at $84,000 for a full course of treatment. Sovaldi was a first ever cure for Hepatitis-C; previous treatments sought to slow the disease's progression, but they didn't cure it and they were expensive. Sovaldi was widely recognized as a cost-effective treatment, improving quality of life for patients and lowering overall costs to the health care system. But the upfront cost still caused understandable outrage, and without competition and with enough demand, it remains true that however reasonable Gilead's price may have been, there was little downward pressure on Gilead's pricing decisions. Nevertheless, Sovaldi is not an example of market failure. Rather, within two years, competitors Merck and AbbVie had also introduced comparable Hepatitis-C treatments. And by February 2015, Gilead had cut Sovaldi's list price by 46 percent in the face of these competing products. Under H.R. 3, however, Sovaldi would be considered to lack competition because those other drugs are not generic copies. Rather, they are other brand-name drugs that are similar in their curative effects. Thus, even though Sovaldi faces competition from similar products, treating the same condition, for the same population, resulting in demonstrable price concessions, H.R. 3 seems to consider this situation a market failure.

Third, the scope of the proposal is broader than it might first appear. While the Secretary is required to negotiate for 25 drugs annually, they can choose to negotiate for as many of the 250 eligible drugs as they are capable of. Considering that the Food and Drug Administration (FDA) approves an average of 33 novel drugs a year,[v] it seems likely that eventually every single new drug would end up included in this negotiation process. That is, every drug would have an absolute maximum price, set by statute, of 120 percent of the AIM price, and all drugs would be capped at the rate of inflation. Ultimately, there would be a government mandated price for every drug, regardless of the population's therapeutic needs or the underlying bio-pharma economics.

Ultimately, at a very basic level, under H.R. 3, the government would set the parameters for the negotiation. The government would determine whether a manufacturer had complied with those parameters. And the government would level substantial penalties on

manufacturers who do not comply with its price concession demands. The more one drills down, the clearer it becomes that the process envisioned cannot be reasonably called a negotiation. The power differential between the two parties is too dramatic.

The Average International Market Price

Returning to what is effectively H.R. 3's price ceiling, the AIM price, a deeper dive seems worthwhile. There is no doubt that other countries pay less for medications than does the United States. There are myriad reasons for this fact, but it remains a frustrating reality for policymakers, the public, and most likely drug manufacturers themselves. Further, there are, unfortunately, few easy solutions to this problem that are without negative implications for U.S. patients.

H.R. 3 proposes to determine the AIM price for targeted drugs based on a volume-weighted average price of the drugs in Australia, Canada, France, Germany, Japan, and the United Kingdom. Manufacturers selected for the negotiation process by the Secretary would then be limited in what they could charge for the drug in question to no more than 120 percent of the AIM price. In effect, the proposal imports foreign price controls as a baseline for setting U.S. drug prices. While it is difficult at this juncture to evaluate the full impact of this specific proposal, the Trump Administration has proposed something similar, the International Price Index (IPI) which would cap the price of some Part B drugs at 126 percent of an index of 14 countries, including the countries selected for the AIM price. It is worth looking at some of the implications of IPI to better understand the potential ramifications the AIM price.

Impacts on Innovation

According to analysis by AAF's Tara O'Neill Hayes in comments to the Centers for Medicare and Medicaid Services (CMS) on the IPI proposal, if the demo were applied to all Part B drugs, expenditures for which now equal nearly $30 billion, revenues would be reduced approximately $9 billion per year.[vi] We have seen historically that reduced revenues do have significant impacts on future investment and development decisions. Pharmaceutical development is an inherently risky proposition, and substantial return on investment is necessary to attract investor capital. To make the point, in 1986, research and development spending by pharmaceutical firms in Europe exceeded that of the U.S. by roughly 24 percent.[vii] As European countries began restricting prices, investment by pharmaceutical companies began to decline in those countries, while investment in drug development in the U.S. expanded. Considering that the cost of successfully bringing a drug to market has been estimated at approximately $2.87 billion,[viii] the $9 billion in lost revenue per year potentially attributable to the IPI proposal would be equivalent to the cost of three new

medicines each year. In the case of the AIM price, the figure would be set at 120 percent of the index, rather than 126 percent in the IPI proposal, and the capped price would be applied to all U.S. payers rather than limited to Medicare Part B, which accounts for only 10 percent of all drug expenditures in the United States.[ix] If the effect on drug development of the AIM price is similar to the impact of the IPI, expanding those effects to 100 percent of the U.S. market would be the equivalent of 30 fewer drugs a year, which is as previously noted nearly the average number of new drugs approved by the FDA annually.

Access to Treatment

As further detailed in Haye's comments to CMS, in the United States, 89 percent of all 290 new medicines and 96 percent of the 82 new cancer medicines launched between 2011 and 2018 were available within three months. In the 14 countries that CMS has identified for inclusion in the IPI proposal, even after adjusting for population, only 51.5 percent of all new medicines and 59.7 percent of new cancer drugs are available in these 14 countries within 17.4 months. Of the 54 new medicines launched during this same period covered under Medicare Part B, only 28, on average, are available in all 14 countries, and it took an average of 18 months for access to be granted after their initial launch.[x] Other countries that seek to limit drug spending through restrictive government price controls have made the determination that lower spending is more important than access to the range of innovative new drugs. Having the government decide that Americans should not have access to new, innovative treatments in a timely manner because the value of those treatments is not worth the cost to tax payers, or in this case private payers as well, has long been a bridge too far for both American patients and policymakers. Changing that calculus would be a sea change. Markets provide an effective means for determining value to consumers, one that policymakers should be reticent to eliminate.

Lowering Drug Spending

In the face of rising demand, the only way to reduce prices without harming innovation or access to treatments is to increase supply and heighten competition. H.R. 3 does nothing to increase the supply of drugs or the level of competition in the market. Effectively, H.R. 3 gives the federal government the power to fix the price of specific medications at a dollar figure determined by federal bureaucrats. This price fixing will invariably have implications for both innovation and access to treatment. It is often argued that manufacturers will continue to invest in R&D because, after all, bringing new treatments to market is their business. It is necessary to remember, however, that manufacturers depend on investment capital. Federal policies that dramatically curtail return on investment will have a detrimental effect on manufacturer's ability to attract the capital necessary to continue bringing new treatments to market. Instead policymakers should look to expand supply and

competition.

The FDA has helped in this undertaking by approving a record number of generic drugs and biosimilars.[xi] But other barriers to unlocking robust market competition remain.

Barriers to Entry

Manufacturers of innovator drugs rightly and understandably want to protect their market share as long as possible. As discussed, bringing a drug to market is a risky and expensive endeavor, and investors need the promise of a formidable profit to be incentivized to make that investment. And there can be no generic without first having the expensive innovator drug. The needs of the investors to receive a return, however, must be balanced with the needs of the consumers and taxpayers to afford those drugs in order for the market system to remain sustainable. There are obvious incentives for brand-name manufacturers to extend the length of their market exclusivity through various means. Congress can scrutinize the opportunity to create entry barriers, such as brand-name manufacturers allegedly abusing the REMS system and, if appropriate, legislate to help even more generics come to market quickly.[xii] (One such example is the CREATES Act.)

Legal Enforcement of Competition Policy

Another challenge is the case of single-source generics. Often, once a generic drug has been on the market long enough, it acquires enough of the market share that the brand-name manufacturer stops producing its version of the drug. In many cases, the price reaches a low enough point that other generic competitors also exit the market, leaving a sole manufacturer. In some high-profile cases, we see what amounts to abuse of monopoly power—that sole manufacturer taking advantage of its position and dramatically increasing its price once there is no more competition and consumers have no choice but to purchase the now high-priced drug. Congress could look at incentives for second manufacturers and accelerating approval of competitor products when such incidences arise.

C**onclusion**

It is also important to recognize that a shift to tighter regulation of pharmaceutical pricing would involve tradeoffs. Other countries that employ such approaches do not have timely access to the breadth of pharmacological breakthroughs that U.S. patients enjoy. If the federal government were to take a more directed approach to managing drug spend, such as those proposed by H.R. 3, it would almost certainly lead to two types of access issues. The first is simply a question of whether manufacturers would continue to produce and sell targeted products at the government-established price. In other countries that dictate prices, manufacturers have answered this question negatively, leading to reduced access to

treatments when compared with the United States. Second, policies aimed specifically at drugs with particularly high prices threaten to upend incentives for the most innovative new medical treatments, which often by their very nature are more expensive to develop and produce, and increasingly serve smaller patient populations. Federal policymakers have historically been reticent to actively limit public program beneficiaries' access to the medications they and their doctors determine to be best. H.R. 3 would potentially limit access for all U.S. patients.

[i] https://www.kff.org/medicare/press-release/people-on-medicare-will-be-able-to-choose-among-24-medicare-advantage-plans-and-27-medicare-part-d-drug-plans-on-average-during-the-open-enrollment-period-for-2019-new-analyses-find/

[ii] https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/03-03-wyden.pdf

[iii] https://www.americanactionforum.org/research/competition-and-the-medicare-part-d-program/#_ftn7

[iv] https://www.americanactionforum.org/research/redesigning-medicare-part-d-realign-incentives-1/

[v] https://www.fda.gov/media/120357/download

[vi] https://www.americanactionforum.org/comments-for-record/comments-to-cms-on-proposed-international-pricing-index-for-medicare-part-b-drugs/

[vii] https://www.nber.org/papers/w12676

[viii] https://csdd.tufts.edu/csddnews/2018/3/9/march-2016-tufts-csdd-rd-cost-study

[ix] https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical.html

[x] "New Medicines Availability in IPI Countries vs United States," PhRMA analysis of IQVIA Analytics Link and FDA, EMA, and PMDA data. December 18, 2018.

[xi] https://www.fda.gov/NewsEvents/Newsroom/FDAInBrief/ucm625627.htm

[xii] https://www.biopharmadive.com/news/congress-creates-act-generic-branded-samples/543147/