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Statement before the House Committee on Energy and Commerce

Testimony on HR 3 and Other Drug Pricing Reforms

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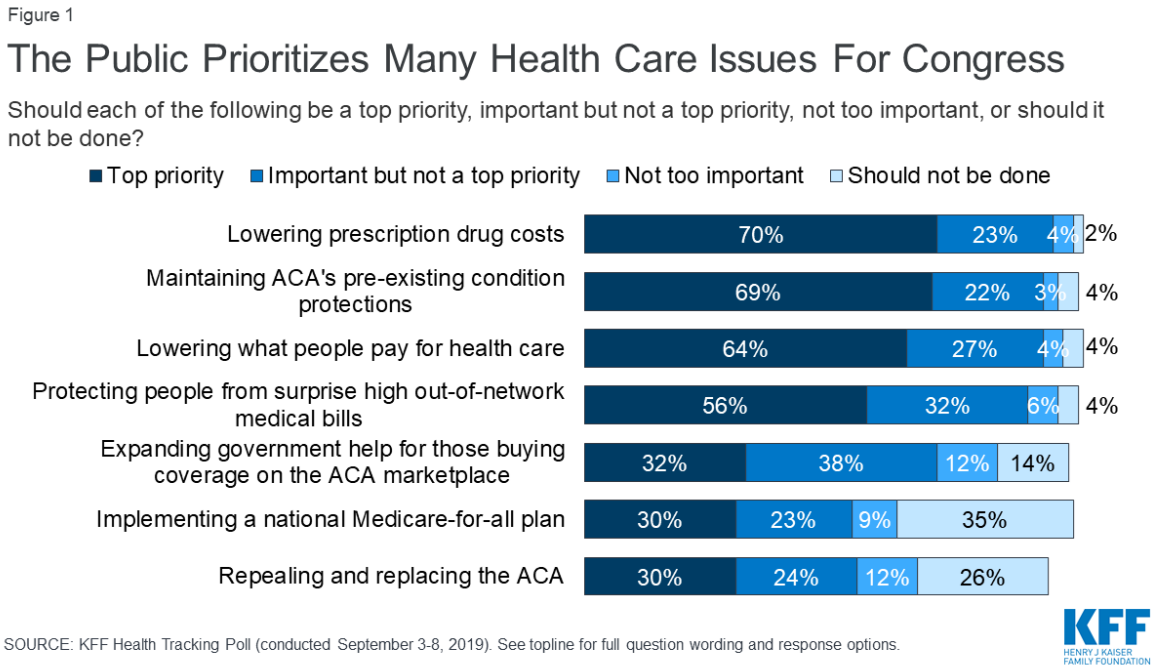
Subcommittee Chairwoman Eshoo, Subcommittee Ranking Member Burgess, Chairman Pallone, Ranking Member Walden, and members of the Committee, thank you for the opportunity to testify today on efforts to reduce the financial burden of prescription drugs. My name is Benedic Ippolito—I am an economist and research fellow at the American Enterprise Institute.

Prescription drugs can offer tremendous benefit to Americans, but they can also represent major financial burdens to patients. Indeed, Americans regularly list reducing prescription drug prices as one of their top policy priorities.

Figure 1



So, I am glad that this Committee, and others in both chambers, are considering this issue so seriously. In my testimony I will focus on two elements of recent proposals: Redesigning the Medicare prescription drug benefit, known as Medicare Part D, and allowing for the Secretary of Health and Human Services (HHS) to negotiate drug prices.

RESTRUCTURING THE MEDICARE PART D BENEFIT

The design of the Medicare Part D benefit has attracted criticism for justifiable reasons. Under its current structure, insurers have very little incentive to control spending and enrollees have no maximum on the amount they spend out of pocket. Moreover, drug manufacturers can take advantage of the current benefit design through creative pricing strategies. This both raises costs to the federal government, and in turn taxpayers, and exposes beneficiaries to the kind of financial risk that insurance is supposed to mitigate. As MedPAC notes, because plan sponsors are not liable for much benefit spending in the coverage gap, Part D's structure may provide a financial advantage to sponsors when they select certain drugs with high prices and large post-sale rebates over lower cost alternatives."[1] In Aaron et al. (2019),[2] co-authors and I elaborated on this point:

> The federal government subsidizes 74.5 percent of the cost of Part D coverage. But the subsidy comes in two forms—a direct subsidy to premiums and through reinsurance. For any beneficiary's spending in the catastrophic range (after the coverage gap), Medicare reinsurance pays for 80 percent of spending. Over time as more very expensive drugs have come into use and prices for brand name drugs have increased, reinsurance has grown from 31.3 percent of basic benefits in 2007 to 72.5 percent.
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> Between the 80 percent reinsurance and beneficiary coinsurance in this range of 5 percent, insurers are responsible for only 15 percent of drug spending in the catastrophic range. This is on top of diluted incentives for prudent spending in the coverage gap, where pharmaceutical manufacturers are now required to offer a 70 percent discount. The two together have the potential to severely distort insurer incentives. Insurers have little incentive to manage drug use through prior authorization, to secure lower list prices for expensive drugs used by their sickest patients, or to encourage the use of generic drugs or less expensive therapeutic alternative branded drugs.
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> MedPAC has proposed reducing the reinsurance percentage from 80 percent to 20 percent, while revamping the risk adjustment model used. This would substantially increase incentives on Part D insurers to contain costs, with the government reaping 74.5 percent of the savings and beneficiaries getting the remaining 25.5 percent.[3]

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[1] Medicare Payment Advisory Commission. "Report to Congress: The Medicare prescription drug program (Part D): Status report." March 2019.

[2] Aaron, Henry, Joseph Antos, Loren Adler, James Capretta, Matthew Fiedler, Paul Ginsburg, Benedic Ippolito, Alice Rivlin. Cost-Reducing Health Policies: A Response to Chairman Alexander and the Senate Committee on Health, Education, Labor, and Pensions." March 1, 2019.

[3] MedPAC. 2018. "The Medicare Prescription Drug Program (Part D): Status Report." Report to the Congress: Medicare Payment Policy, Chapter 14. March 2018.

Recent proposals like the Lower Drug Costs Now Act (LDCNA) and the Prescription Drug Pricing Reduction Act (PDPRA) include substantial redesigns to this benefit that would reduce open-ended federal spending, improve incentives to control overall costs, and place a cap on the maximum out of pocket spending of enrollees. Specifically, proposed redesigns would largely close the donut hole and place far more liability on insurers in the catastrophic phase of the benefit, among other changes. This would give insurers much stronger incentives to manage total spending and lessen the incentives to prefer drugs with high list-to-net pricing spreads. This redesign of the Part D benefit should work to incentivize the use of more cost-effective drugs rather than those that most effectively offload costs onto the federal government through reinsurance payments. I believe these are exactly the kind of policy changes that should be encouraged.

I am not alone in this view. While there are some differences across proposals, in general, they incorporate some of the recommendations that MedPAC has long suggested.[4] In addition, proposed changes mirror some of those suggested to the Senate earlier this year by a bipartisan group of health policy experts from the American Enterprise Institute and the Brookings Institution[5]—an effort of which I was a part.

DRUG NEGOTIATION PROPOSALS

I am more concerned about proposals to allow the Secretary of HHS to negotiate drug prices, as the LDCNA, among other proposals, have suggested. In this section of my testimony, I discuss a few of the specific concerns I have with allowing the secretary to set prices.

[4] "Report to the Congress: Medicare and the Health Care Delivery System. Chapter 6 Improving Medicare Part D." MedPAC June 2016.
[5] Aaron, Henry, Joseph Antos, Loren Adler, James Capretta, Matthew Fiedler, Paul Ginsburg, Benedic Ippolito, Alice Rivlin. Cost-Reducing Health Policies: A Response to Chairman Alexander and the Senate Committee on Health, Education, Labor, and Pensions." March 1, 2019.

Challenges with Price Setting

In many cases, these proposals effectively task the Secretary with dictating a price. Under the LDCNA, for example, the penalties associated with walking away from the negotiating table can easily exceed net revenues flowing to a firm. In other proposals, firms could even lose their intellectual property. As such, the prices paid in the entire U.S. market will be largely at the discretion of a very small number of bureaucrats who can interpret this relatively general guidance how they see fit.

Consolidating price setting power this much introduces a number of challenges. This is particularly true under the practical reality that rate regulators cannot feasibly know all relevant information distilled via markets and where they are subject to substantial constraints and pressures—be them political or otherwise. Centralized decision making under these kinds of scenarios can lead to outcomes that stray far from what is the best for Americans. This is important to acknowledge because there are real costs to erring in price setting.

Tradeoffs Between Lower Prices and Innovation

The economics literature has repeatedly shown what likely seems obvious—financial returns for successful drugs has a direct influence on the research and development decisions of firms.[6,7,8] As Craig Garthwaite and I noted earlier this year in STAT, this phenomenon is evident when considering the case of two diseases, malaria and gout:

> Malaria, a mosquito-borne illness, afflicted more than 200 million people in 2016, resulting in nearly 450,000 deaths. Gout, a buildup of uric acid in the joints, causes

[6] Acemoglu, Daron and Joshua Linn. "Market Size in Innovation: Theory and Evidence from the Pharmaceutical Industry." *The Quarterly Journal of Economcs*. Vol 119, Issue 3, August 2004, pages 1049-1090.
[7] Amy Finkelstein. "Static and Dynamic Effects of Health Policy: Evidence from the Vaccine Industry." *The Quarterly Journal of Economics*, Volume 119, Issue 2, May 2004, Pages 527–564.
[8] Dubois, Pierre, Olivier De Mouzon, Fiona Scott-Morton, and Paul Seabright. "Market size and pharmaceutical innovation." *The RAND Journal of Economics*, 46, no. 4 (2015): 844-871..

> exceptionally painful swelling. Made worse by the consumption of fatty foods and alcohol, gout has been called the "disease of kings." While painful, gout is not fatal.
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> From a global welfare perspective, we arguably should be investing massive resources into a cure for malaria. Yet between 2004 and 2016, only nine clinical trials for malaria were publicly registered, compared to 239 for gout. The reason for this is obvious — the average per capita gross domestic product of countries where malaria is endemic is less than $2,000, while gout is more common in countries with populations of relatively affluent and insured individuals.

This profit-innovation tradeoff is particularly relevant for the United States. According to data from IQVIA, the United States accounts for about 60 percent of drug spending in the developed world.[9] This means that the United States faces much starker tradeoffs between spending and future drug development than other countries. Because our market is so large, changes in spending will have first order implications for the types of drugs available in the future. The LDCNA includes a number of such tradeoffs.

For example, in cases where politicians emphasize four- or eight-year time horizons, there will be substantial pressure for the Secretary to sharply reduce current prices and enjoy the immediate benefit of lower spending in the short term, while discounting the tradeoffs of reduced innovation that is only realized beyond the time horizon that is prioritized. From a societal perspective, this is not optimal.

In addition, consider the incentives associated with the LDCNA's negotiation process. Drugs that have no competitors would be subject to aggressive rate regulation by the Secretary. The same is not true of drugs with at least one such competitor. It is entirely possible that being a second market entrant could prove substantially more profitable than bringing a novel therapeutic to market. Thus, the proposal could substantially depress incentives to pursue pathbreaking drugs. This

[9] "The Global Use of Medicine in 2019 and Outlook to 2023: Forecasts and Areas to Watch." IQVIA. Institute Report. January 29, 2019.

is particularly true of drugs that treat relatively small populations and are unlikely to face competition in the near future. It is worth asking whether these are the kinds of incentives we want to establish.

In addition, I worry about the unpredictability of such a system. Depending on political leanings or policy preferences of future administrations, rate regulation of this type could look very different over time. One might, for instance, predict considerably different use of this type of pricing power under an administration led by Senator Bernie Sanders than under, say, the Bush administration that enacted Medicare Part D. This is particularly pertinent because many proposals only include vague guidance to future regulators. This kind of uncertainty is very costly from the perspective of pharmaceutical firms who must make decisions about very long-term investments.

If Congress believes that incentives to invest in certain kinds of drugs are too high, then I recommend incentives or policy changes that convey clear signals to market actors and which allow policymakers to weigh tradeoffs appropriately. Recently proposed reforms to Medicare Part D embody this concept. Most proposals would highly curtail open-ended government reinsurance for high-cost drugs and limit the incentives to engage in certain kinds of strategic pricing. This should encourage more efficient cost management by insurers, but will likely also alter incentives facing manufacturers. This is likely to shift incentives away from pursuing very high-cost therapies towards lower cost primary care drugs.[10] Should a redesign like this become law, incentive changes are relatively clear and predictable for both policymakers weighing the welfare implications of such a change, and for firms making investment decision.

Challenges with Using International Reference Pricing

[10] Gottlieb, Scott, Benedic Ippolito, and Abigail Keller. "Understanding the impact of the newly proposed Senate drug pricing legislation on manufacturers' investment decisions." AEIdeas. September 9, 2019.

The existence and importance of this tradeoff is one reason United States ought to not abdicate decisions over drug prices to other countries through reference pricing. Again, Garthwaite and I note:

> [T]he simple fact that the U.S. pays more for drugs than other countries does not prove that our prices are too high, nor should we implicitly assume that international prices represent the appropriate balance of tradeoffs. Many of these countries have long had the luxury of enjoying innovations made possible by U.S. profits.

By importing the pricing decisions of other countries, we are importing preferences over what is, or what isn't, worth paying for that may differ substantially from ours—particularly because these countries do not face the same downsides to setting prices too low. However, the fact that foreign countries have not faced the same tradeoffs as the United States is not the only reason international reference pricing concerns me. I have further hesitations about the feasibility of reliably calculating reference prices which, for example, constrain negotiations in H.R. 3. Specifically, under that proposal, the maximum fair price could be no higher than 120% of the average price in six countries (Australia, Canada, France, Germany, Japan, and the United Kingdom). The volume-weighted net price in these countries is referred to as the Average International Market Price. I do not think it will be trivial to reliably calculate this price.

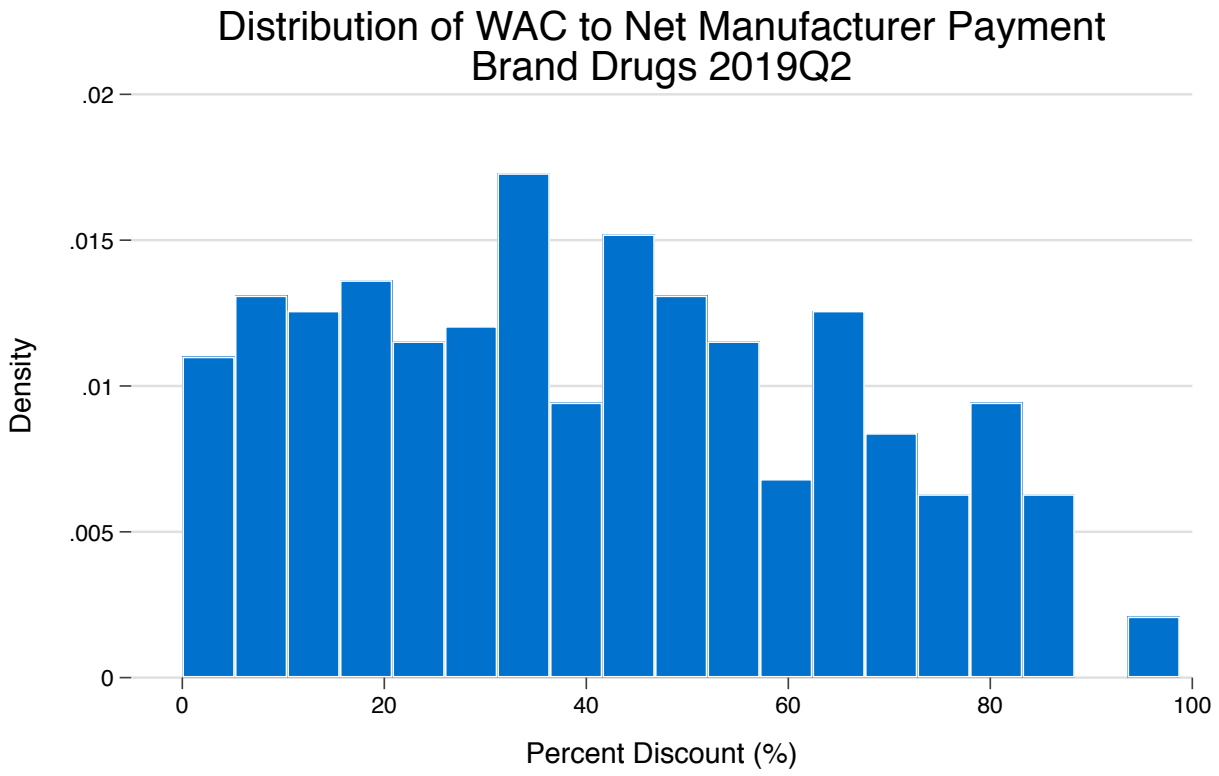
First, firms will have a strong incentive to act strategically to keep US prices high through a number of channels. For example, drugs are typically offered in a host of different doses, package sizes, or delivery mechanisms. Firms would likely attempt to take advantage of this fact by offering certain dose-package size combinations selectively in reference countries, but not the United States. In addition, it is not trivial to measure actual transaction prices in foreign countries. As Brandt (2013) notes, "[p]rice comparisons are in some cases also further complicated by differences between ex-factory prices, wholesale prices and retail prices as well as currency fluctuations and exchange rate volatility." And further, "the indicated prices might not reflect the actual prices at which pharmaceutical companies sell the drugs to public authorities. Confidential discounts in the

contracts are common.[11]" Should U.S. prices be tied to an international reference price, manufacturers and reference counties could, for instance, agree to higher observable prices in exchange for increased non-salient price discounts aimed at keeping actual international prices low and American prices high. Determining a true transaction price in foreign countries could prove to be extremely challenging. (It is perhaps because of these complexities that H.R. 3 notes that the AIM price will be the volume-weighted, net price "if practicable.")

To get a sense for the complexity of accurately measuring drug prices, it is worth considering pricing trends domestically. Drugs have a Wholesale Acquisition Cost (WAC) which is analogous to the Manufacturer's Suggested Retail Price (MSRP) for item of clothing or other good. This price is easily ascertained. Importantly, however, drug list prices do not represent the typical transaction price for many domestic purchasers. Drug manufacturers offer a complex series of ex-ante and ex-post price concessions to purchasers which reduce the actual transaction price at various points in the supply chain. These concessions can relate to a host of considerations like the volume or market share of a drug sold to a purchaser, preferential formulary placement, or statutorily defined rebates to some public payers. Historically, list prices were close to transaction prices, however, large rebates are now common. Below, I use data from SSR Health to show the difference between list prices and payments to manufacturers for branded drugs in the domestic market.[12]

[11] Brandt, Lisa. Price tagging the priceless: international reference pricing for medicines in theory and practice. No. 4/2013. ECIPE Policy Brief, 2013.

[12] Specifically, I use data from the SSR Health Brand Net Price Tool. I restrict my sample to the most recent quarter—the second quarter of 2019. This dataset includes information about branded drugs from publicly traded pharmaceutical firms and covers over 90 percent of single-source net sales. The data include list prices (WAC price) and an estimate of net payments to manufacturers. Net payments are estimated using financial disclosures of publicly traded firms, data on volume from Symphony Health Solution, and a simplifying assumption about inventory. I exclude drugs with very small market shares (less than $1 million per quarter). Note that these data are inclusive of all discounts, including statutorily required discounts like those in Medicaid. N=367.



The mean difference between list and net payments to manufacturers is 40 percent in this sample. Net payments for some drugs are under 5 percent of the drug's list price, while in other cases it is above 90 percent. While restricted to the domestic market, this hints at the highly complex drug pricing environment. Accurately measuring net prices at the product level across a host of countries will be a very challenging undertaking.