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**BEFORE THE U.S. CONGRESS
HOUSE COMMITTEE ON EDUCATION AND LABOR
Subcommittee on Health, Employment, Labor and Pensions**

Congressional Hearing, September 26, 2019

**"MAKING HEALTH CARE MORE AFFORDABLE: LOWERING
DRUG PRICES AND INCREASING TRANSPARENCY"**

Statement of

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Chairwoman Wilson, Ranking Member Walberg, and members of the Committee, good afternoon. It is a great honor to be speaking with you today. My name is Mariana Social, and I am a medical doctor. I have a Ph.D. in Health Systems from the Johns Hopkins University and a master's in Public Policy from Princeton University.

I am currently a faculty member in the Department of Health Policy & Management at the Johns Hopkins Bloomberg School of Public Health. My primary research interest is how to improve access for people who need prescription drugs to improve their health and quality of life.

For over a year, I have been partnering with the Pacific Business Group on Health – a “purchaser coalition representing 60 public and private organizations across the U.S that collectively spend \$40 billion a year purchasing healthcare services for 10 million Americans”¹ - to improve the drug benefit that they provide to their members by identifying and removing wasteful drug spending from their drug formularies.

I also lead a research project in partnership with ERIC – The ERISA Committee. ERIC represents large plan sponsors - generally nationwide companies with over 10,000 employees—that “provide comprehensive employee benefits to workers

¹ <http://www.pbgh.org/about/members>



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and families across the country.”² In this project, we are examining prices paid by 10 of the largest US corporations for biologic and biosimilars. These companies have asked us to analyze their information because they are concerned that they may not be getting the best deals that they can.

I am speaking today on my own behalf. The opinions expressed herein are my own and do not necessarily reflect the views of The Johns Hopkins University.

I would like to provide commentary on how high drug prices impact American employers and their workers, and American retirees.

PART I – HOW HIGH DRUG PRICES IMPACT AMERICAN EMPLOYERS AND THEIR WORKERS, AS WELL AS RETIREES

Most Americans obtain health coverage through their employers

Currently, 55% of all Americans obtain health coverage through their employer³ and 61% of those individuals are covered by employer self-

² <https://www.eric.org/about-eric/>

³ US Census Bureau - Health Insurance Coverage in the United States: 2018

<https://www.census.gov/content/dam/Census/library/publications/2019/demo/p60-267.pdf>



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sponsored insurance plans.⁴ This means that the prescription drug costs of most American workers are paid directly by their employer.⁵ However, recently many companies are pushing more and more of the costs of prescription drugs onto the employees. This one of the reasons why members of Congress are hearing more about the cost of prescription drugs.

Self-insured employers take a financial risk to cover their employees

Given the high number of Americans who depend on self-insured employers to obtain their coverage, and the financial risk that these employers and employees are taking, it is imperative to keep prescription drug costs under control. Today, prescription drug prices are on the rise and this means that many Americans are not able to afford the drugs they need, even if they have health insurance.

Today, most employers negotiate drug prices through a PBM

The typical self-insured employer hires a pharmaceutical benefit manager – PBM – to manage their drug benefit. The PBM negotiates prices with the

⁴ Kaiser Family Foundation Employer Health Survey 2018
<https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>

⁵ Self-insured employers may purchase stoploss insurance, which may cover varying portions of the risk. (reference: Kaiser Family Foundation survey)



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drug manufacturers and, based on these negotiations, the PBM designs the drug formulary that determines the employer's drug benefits.

PBMs must have the ability to say “no” in order to successfully negotiate

In order to obtain a lower price for a certain drug, the PBM will offer to place that drug in a favorable position in the formulary – at lower cost sharing or without any clinical requirements for utilization. Often, in exchange for a lower price, the PBM will also agree to exclude the drug's competitors from the formulary. Thus, the ability to say "no" and exclude certain products from the formulary is *crucial* for the success of most price negotiations performed in America today. When the PBM has a choice, and therefore the ability to negotiate, the market can work. This occurs when there are both branded and generic products available in the market for the same drug, or when there are many similarly effective drugs available in the same therapeutic class.

The market fails when there is no competition

The problem occurs when there is no competition because the drug is the only option available in the market. This may occur even for drugs that have been on the market for a long period of time. Drugs can keep their competitors off the market by instituting pay-for-delay agreements, for



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example, or by extending their patent life by implementing tweaks to their chemical composition, to their administration mechanism, and so on. Insulin, for example, is an unpatented drug, but its administration devices are protected by patents. In some cases, the market is small and even if the drug is not protected by a patent, there is not enough incentive for a competitor to enter the market. In these situations, especially if the drug is the only one that treats the disease, prices remain high because the PBM cannot negotiate lower prices and drug manufacturers do not have an incentive to offer a lower price.

The US pays much higher drugs prices than other countries for certain drugs

My colleagues and I examined the 79 top-spending drugs in the Medicare that had no generics or biosimilars available.⁶ These drugs alone were responsible for over 50% of the total part D program spending in 2016. We compared the U.S. prices of these drugs to the prices in the UK, in Japan and in Ontario, Canada. We found that, on average, U.S. prices were 3 to 4 times higher than the prices in other countries, for the same drugs. Interestingly, drugs that were "older," i.e., were available in the US market for longer, had higher price differentials when compared to other countries.

⁶ Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D To Reduce Drug Price Differentials With Other Countries. *Health Aff (Millwood)*. 2019 May;38(5):804-811.



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US drug rebates do not offset the price differential with other countries

In our analysis, we accounted for drug rebates paid by drug manufacturers. We found that, in order for the US price to match the average price of the other countries, drug manufacturers would have to offer an average rebate of approximately 78% for the drugs that we studied in the US. Drug rebates are confidential, and so we could not verify manufacturer's actual behavior. However, it is unlikely that drug manufacturers would provide such high rebates to all drugs that we studied because these drugs lacked direct competition. The numbers published by Medicare show average rebates for branded drugs in the low 20%⁷, and an independent analysis by the IQVIA institute found average rebates in the Medicare program of approximately 35% for branded drugs.⁸

List prices, before rebates, determine Americans' cost-sharing amounts

Even if a manufacturer were to offer a large rebate to the PBM or self-insured company on one of these high-cost drugs, the problem is that the level of cost sharing by the American worker is determined by the drug's list prices before rebates are applied. The Associated Press reported in the first 7 months of 2018 that drug companies were 96 times more likely to increase the list price

⁷ CMS. 2014 Part D Rebate Summary for All Brand Name Drugs. https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/PartD_Rebates.html

⁸ IQVIA institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf>



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than to lower the list price.⁹ Today, American workers are increasingly required to pay a percentage of the list price of their drugs, especially for high-cost specialty drugs.

In the Medicare program, it is estimated that 63% of beneficiaries are enrolled in a plan that charges a percentage coinsurance for specialty drugs.¹⁰ The result is that, on average, patients pay approximately 22% of the final cost of any given drug.¹¹ This is why it is becoming increasingly hard for Americans to afford drug prices. Patients do not directly benefit from drug rebates because their out-of-pocket payment is typically calculated over the drug's list price.

Out-of-pocket caps alleviate, but do not necessarily resolve the problem

Fortunately, there are out-of-pocket maximums for most employees with employer-sponsored coverage. However, in about 20% of cases, the out-of-pocket maximum is equal to or higher than \$6,000 a year.¹² This amount represents almost 10% of the median household income in America (which,

⁹ <https://www.apnews.com/b28338b7c91c4174ad5fad682138520d>

¹⁰ Medicare's Part D Drug Benefit At 10 Years: Firmly Established But Still Evolving. Hoadley J.F., Cubanski J., Neuman P. *Health Affairs* 34, No. 10 (2015): 1682–1687

¹¹ IQVIA institute. Estimate of Medicare Part D Costs After Accounting for Manufacturer Rebates. October 2016. <https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/estimate-of-medicare-part-d-costs-after-accounting-for-manufacturer-rebates.pdf>

¹² Kaiser Family Foundation Employer Health Survey 2018

<https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>



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according to the US Census Bureau, was \$61,372 in 2017).¹³ In addition, patients pay full list price for their drugs while they are on their deductible phase; this is extremely important for the American workers enrolled in high-deductible health plans. As of 2018, this represented 29% of workers with health insurance.¹⁴

Medicare beneficiaries do not have an out-of-pocket maximum

It should also be noted that, while most employees covered by employer-sponsored health insurance are protected by an out-of-pocket maximum, once they become Medicare beneficiaries they lose this protection. Medicare beneficiaries obtain their drug benefit through the part D program, which does not have an out of pocket limit. There have been multiple proposals to limit the out-of-pocket liability for Medicare beneficiaries, such as a proposal by the Trump Administration, the Senate Finance Bill that passed, and HR 3; these proposals simply disagree on the amount.

PART II – HR3 AND OTHER POLICY CONSIDERATIONS

In sum, high drug prices strain American employers, workers, and retirees. The market does not work for certain drugs because the PBMs have limited

¹³ US Census Bureau <https://www.census.gov/library/publications/2018/demo/p60-263.html>

¹⁴ Kaiser Family Foundation Employer Health Survey 2018

<https://www.kff.org/health-costs/report/2018-employer-health-benefits-survey/>



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negotiating power when there is no competition. For these cases, alternative negotiation pathways are greatly needed. The negotiation mechanisms outlined in HR3 target these drugs for which there is a market failure. In the absence of product-to-product competition within the US market, the price comparison between the US and other countries can offer an alternative pathway for negotiation.

Using international prices as a benchmark can bring the US price back to international norms

Currently, most pharmaceutical manufacturers are global companies and they rely on sales in both US and international markets to obtain their revenue.¹⁵ Using average international market prices as benchmarks for US price negotiations has the potential to generate significant savings for US employers and their employees. Our analysis of the 79 top-spending drugs in Medicare part D found that, if the US paid the average price across the countries that we studied, the Part D program alone could have saved \$72.9 billion dollars in 2018.¹⁶ If employers adopted this approach the savings would be similar

Which countries should be included in the international price?

¹⁵ <https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf>

¹⁶ Kang SY, DiStefano MJ, Socal MP, Anderson GF. Using External Reference Pricing in Medicare Part D to Reduce Drug Price Differentials With Other Countries. *Health Aff (Millwood)*. 2019 May;38(5):804-811.

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It is important to select countries that have similar per capita incomes and large pharmaceutical markets like the US to be included in the international price. Ideally, these countries would also have diverse price-setting approaches. For example, some countries such as the UK have value-based pricing, whereas other countries such as Germany have market-based pricing. Our research found no major differences when prices from other countries were compared with each other. The patterns that emerged in our data suggest that, although countries may have different mechanisms for setting or negotiating drug prices, ultimately they obtain drug prices within the same range.

There is strength in numbers: price negotiations involving more individuals result in lower drug prices

Currently, negotiations for most covered Americans are fragmented between drug manufacturers and each one of the PBMs, Medicare prescription drug plans, Medicare Advantage plans, and so on. HR 3's proposal of having the HHS Secretary negotiate on behalf of all Medicare beneficiaries and those covered by private insurers, including by self-insured employers, would greatly increase the negotiation power because it would cover the vast majority of Americans. Combining larger numbers of individuals in a single negotiation has been shown to increase negotiating power and result in lower drug

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prices.¹⁷ In addition, companies can opt out of the negotiated price, which is a critical element of this proposal.

Experience suggests that the HHS Secretary can successfully negotiate prices

The experience of governmental agencies such as the Department of Veterans Affairs and the Department of Defense provides a solid example in support of the HHS Secretary successfully negotiating drug prices. These agencies have negotiated drug prices on behalf of their beneficiaries for years and have obtained the lowest prices in America today.¹⁸ It is estimated, for example, that the VA pays 44% less than Medicare for a same basket of drugs.¹⁹

There is strong public support for allowing the HHS Secretary to negotiate drug prices

The Kaiser Family Foundation performs a periodic survey of the American public to examine the public's opinions, knowledge, and experiences on

¹⁷ Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. <http://www.nber.org/papers/w15330>

¹⁸ GAO-13-358. Prescription Drugs: Comparison of DOD and VA Direct Purchase Prices. <https://www.gao.gov/products/GAO-13-358>

¹⁹ Venker B, Stephenson KB, Gellad WF. Assessment of Spending in Medicare Part D If Medication Prices from the Department of Veterans Affairs Were Used. *JAMA Intern Med.* 2019;179(3):431-433.



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various issues related to the U.S. health care system.²⁰ In February 2019, the Kaiser Family Foundation survey found that 86% of the general public and 82% of Americans aged 65 and older supported allowing the federal government to negotiate with drug companies to get a lower price for people on Medicare.

Having the HHS Secretary negotiate drug prices would benefit employers

Currently, many Medicare prescription drug plans are managed by the same PBMs who manage the drug benefit for private plans, including for self-insured employers.²¹ This means that when PBMs can't negotiate effectively for Medicare plans, they can't negotiate effectively for private plans, and vice versa.

Employers need help getting good prices for high-cost drugs

US companies, especially very large employers, like to think that they are getting the best possible deals from their PBMs. However, this is not always the case. We were asked by ERIC, the Committee that represents large

²⁰ KFF Health Tracking Poll – February 2019: Prescription Drugs. <https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/>

²¹ Insurer bargaining and negotiated drug prices in Medicare Part D. Lakdawalla D., Yin W. NBER Working Paper 15330. <http://www.nber.org/papers/w15330>

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nationwide employers who are also plan sponsors, to examine the prices that 10 of the largest US corporations were paying for biologics and biosimilars. The first thing that we found was that the PBMs did not always give these companies the information they needed to determine if they were getting a good deal. When we finally got the data, we found that two companies of the same size and using the same PBM were paying about 10% different prices for a same high-cost biologic drug.²²

Employers and workers are spending unnecessarily high amounts on branded drugs. Increased price transparency can help reduce that

PBMs have a financial incentive to keep high-cost, high-rebate drugs in employers' drug formularies. This is because, for branded drugs, PBMs can make a profit by retaining some portion of the rebates plus any fees that they obtain from drug manufacturers, and drugs that are more highly priced can generally offer greater rebates. Therefore, drugs that have high prices and high rebates may be favored in the formulary in detriment of lower-cost alternatives. In the Medicare program, for example, we found that 70% of part D prescription drug plans had placed at least one branded drug more favorably than its corresponding generic in the formulary.²³ This increases cost unnecessarily for both plans and beneficiaries. Unfortunately, employers

²² These are initial results from an ongoing research project and have not been published.

²³ Socal MP, Bai G, Anderson GF. Favorable Formulary Placement of Branded Drugs in Medicare Prescription Drug Plans When Generics Are Available. *JAMA Intern Med.* 2019 Jun 1;179(6):832-833.

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do not always have the full information to identify that these distortions are present in their drug formulary.²⁴

Reducing wasteful spending from high-price high-rebate drugs could save employers up to 24% of their overall pharmacy spending

An analysis of 15 large US companies by the Pacific Business Group on Health, a purchaser coalition representing 60 public and private organizations across the U.S that collectively purchase healthcare for 10 million Americans,²⁵ has shown that reducing the use of high-cost, low-value drugs could save 3% to 24% of a company's *overall* pharmacy spending.²⁶ Having a transparent price for branded drugs available for all employers would increase transparency and would help employers identify where they are spending too much with certain drugs, better equipping employers to identify and ultimately remove wasteful spending from their drug benefit.

²⁴ Bai G, Socal MP & Anderson GF. Policy Options To Help Self-Insured Employers Improve PBM Contracting Efficiency. Health Affairs Blog. May 29, 2019.

<https://www.healthaffairs.org/doi/10.1377/hblog20190529.43197/full/>

²⁵ <http://www.pbgh.org/about/members>

²⁶ Vela, L. Reducing Wasteful Spending in Employers' Pharmacy Benefit Plans.

<https://www.commonwealthfund.org/publications/issue-briefs/2019/aug/reducing-wasteful-spending-employers-pharmacy-benefit-plans>



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Having the option of accessing the HHS-negotiated price would benefit employers in two ways: lower drug prices and increased transparency

Having the option of agency-negotiated price would, first, offer lower prices to employers and to workers who obtain coverage through employer-sponsored health insurance. PBMs would still be allowed to negotiate down prices, bringing additional price reductions into the system. The experience in the Japanese system, where the government negotiates a maximum price and payers obtain further discounts from their own subsequent negotiations, shows that drugs' actual selling prices will be lower than the maximum price in the government fee schedule because of competition among distributors.²⁷ In addition, HR 3 would benefit employers by providing them with a transparent maximum price. Having a transparent pricing benchmark will show employers if they are getting a better deal by opting in or opting out, improving their decision-making.

For patients, greater price transparency may reduce cost-sharing

Currently, when beneficiaries must pay a percentage of the drug cost, the patient's cost-sharing amount is calculated based on the drug's list price (i.e., the price before rebates and discounts are applied). The drug's net price after

²⁷ Ikegami N, Anderson GF. In Japan, All-Payer Rate Setting Under Tight Government Control Has Proved To Be An Effective Approach To Containing Costs.



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rebates and discounts is usually not known at the time that the patient is obtaining their drug and therefore it cannot be used. HR 3 will allow for HHS-negotiated prices to be available at the time that patients are obtaining their drug, allowing these prices to be used in cost sharing calculations. HHS-negotiated prices are likely to be much lower than the list price, which would likely translate to lower cost-sharing amounts for patients.

Having a penalty is an important element to enable the negotiation

The US pays more than other countries especially for drugs that have been on the market for many years. When drugs already have an established market, and there are patients who depend on them, PBMs are less likely to be able to say “no” and remove the drug from the formulary. Therefore, some drugs may exhibit egregious price-hiking behaviors such as Daraprim’s overnight 5000% price increase back in 2015 without concerns for losing market share.²⁸ It is important to have a clear penalty that can prevent these behaviors and ensure that drug manufacturers come to the table to negotiate.

Having an inflationary rebate is an important mechanism to prevent price hikes for drugs that are not eligible or not selected for negotiation

²⁸ <https://khn.org/news/for-shame-pharma-bro-shkreli-is-in-prison-but-daraprim-price-is-still-high/>
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Drugs that are not eligible or that are not selected for negotiation in a given time period may still exhibit price increases that can be detrimental for payers and beneficiaries. HR3 establishes an inflationary rebate that provides an important mechanism to prevent such price increases for branded and generic drugs alike.

In order to protect and reward innovation, new drugs are granted patents that provide a period of time in which the drug has a monopoly i.e., no other competitor may enter the market. Drug manufacturers set the drug's launch price to allow them to recoup their research and development investments during the drug's monopoly period. Price changes that occur after a drug has launched are unlikely to be related to the need to recoup R&D investment.

Other developed countries have mechanisms in place to prevent this type of behavior. In the US, many of today's high-cost drugs originally entered the market at lower prices and have only become expensive over time.

Allowing the HHS Secretary to negotiate drug prices is unlikely to discourage drug innovation

The concern that negotiating prices would discourage innovation comes from the perception that, if pharmaceutical manufacturers were to have lower

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revenue, they would not have sufficient funds to invest in research and development for new drugs. However, there are some facts that speak against this perception.

First, pharmaceutical manufacturers are spending more on drug marketing than on drug research and development.²⁹ Having a strong drug development pipeline is crucial in order to attract investors and remain competitive in the market. Even if manufacturer revenues were to decrease under the new policy, manufacturers would be unlikely to choose to cut spending on drug development when they could first implement cuts to the marketing budgets.

Second, the costs of research and development for each drug are debatable. Median estimates vary from about \$2 billion to a about \$650 million per drug.³⁰ At the same time, estimates suggest that, after four years in the market, a drug will have generated over 9 times higher revenue than its own research and development costs.³⁰

²⁹ Swanson A. Big pharmaceutical companies are spending far more on marketing than research. <https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/>

³⁰ Prasad V., Mailankodi S. Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues After Approval. *JAMA Intern Med.* 2017;177(11):1569-1575. <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2653012>

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Lastly, the federal government, though its agencies such as the National Institutes for Health (NIH), currently funds a significant portion of the research and development costs for pharmaceuticals, especially at the initial phases of drug development, when failure rates are high. If the savings obtained from price negotiations were reinvested, the fraction represented by governmental funding could be significantly increased.

Drug costs are unlikely to shift to other countries if the Secretary uses an international benchmark in the US

Most developed countries have mechanisms in place to negotiate or regulate drug prices.³¹ For example, the UK has a system of value-based pricing based on health technology assessment. In this system, a drug's benefits are compared to the other drugs that are available in the market for the same condition. The drug's price is then determined according to the value that the drug adds in comparison to its therapeutic alternatives. Such mechanisms are unlikely to be influenced by the US decision to include the country's price in the international benchmark. In addition, most countries already reference other countries' drug prices when negotiating or setting drug prices domestically. A potential unintended consequence of this practice, however, is that drug manufacturers could choose to not launch in a certain product in a

³¹ Maniadakis N, Kourlaba G, Shen J, Holtorf A. Comprehensive taxonomy and worldwide trends in pharmaceutical policies in relation to country income status. *BMC Health Serv Res.* 2017; 17: 371.



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given country if they know the country will be used as a reference in order to maintain the average price high. This is mostly a concern when including countries with less developed pharmaceutical markets in the international price. If only major pharmaceutical markets are included in the international price, manufacturers are highly unlikely to choose not to launch their product in that country.

FINAL REMARKS

High drug prices strain American employers, workers, and retirees. Because most Americans obtain health insurance through their employers, lowering US health care costs not only helps bring down premiums and out-of-pocket payments; lower health care costs also contribute to making American workers and corporations more competitive in the global market.

Thank you so much. I look forward to answering any questions that you may have.