February 4, 2020

The Honorable Nancy Pelosi
Speaker
U.S. House of Representatives
Washington, DC 20515

The Honorable Mitch McConnell
Majority Leader
United States Senate
Washington, DC 20510

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, DC 20515

The Honorable Charles E. Schumer
Minority Leader
United States Senate
Washington, DC 20510

Re: Prescription Drug Pricing Legislation

Dear Speaker Pelosi, Leader McConnell, Leader McCarthy and Leader Schumer:

I write on behalf of the American Benefits Council ("the Council") to urge Congress to find common ground and pass legislation that will lower prescription drug costs for working families and seniors alike.

The Council is a Washington, D.C.-based employee benefits public policy organization. The Council advocates for employers dedicated to the achievement of best-in-class solutions that protect and encourage the health and financial well-being of their workers, retirees and families. Council members include over 220 of the world's largest corporations and collectively either directly sponsor or administer health and retirement benefits for virtually all Americans covered by employer-sponsored plans.

Pharmaceutical drug therapies have played a significant role in treating and curing injury, illness and disease. They allow millions of Americans to overcome debilitating conditions, return to work and live longer, healthier, more productive lives. Moreover, money spent wisely on drugs can save money on hospital, physician and other medical expenditures. Although the benefits of pharmaceutical drug therapies are substantial, these benefits often come with significant financial costs to both participants and to payers in the health care system, including employer-sponsored plans. Total retail prescription drug spending in the United States reached $333 billion in 2017, after

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accounting for rebates. Employer-sponsored health plans paid for 42% – $140 billion – of the total prescription drug spend, while Medicare Part D covered 30% and Medicaid covered 10%.[1]

In an effort to manage drug costs, employers have sought to implement innovations and strategies while still ensuring that their employees and the employees' dependents have access to needed drugs and services. Nonetheless, prescription drug costs continue to represent a considerable portion of overall plan costs. In 2017, spending on prescription drugs and medical services obtained at pharmacies was 29% higher than in 2013 for individuals with employer-provided health coverage, not accounting for manufacturer rebates. The increase in spending includes increases in expenditures for existing drugs, as well as increases in expenditures that result from the adoption of newly approved medications.[2] Among employers with 500 or more employees, prescription drug costs growth slowed in 2019, but still outpaces other medical services.[3]

As the largest purchaser of prescription drugs in the United States, employers are deeply concerned about prescription drug costs. Employers are not willing to write a blank check for prescription drugs, nor are they willing to accept the absence of appropriate price – and cost – transparency. The current rebate structure used in the marketplace is complex and opaque for many employers, making it hard for employers as well as plan participants and beneficiaries to understand the true prices of drugs and the true value of how the rebate is calculated.

Bold action is needed to lower prescription drug costs and increase transparency to ensure that public and private payers and patients spend resources more wisely. Accordingly, the Council strongly supports the goal of lowering prescription drug costs, which remain a significant driver of employer plan expenses, and applauds bipartisan focus on solutions. Legislation must not, however, have unintended adverse consequences for employer-sponsored coverage. The Council also believes that any legislative solution should be part of an overall, collaborative effort among Congress, the executive branch and stakeholders to lower drug costs and ensure continued access to clinically effective — and cost-effective — pharmaceutical drug therapies.

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[1] https://www.kff.org/medicare/issue-brief/how-does-prescription-drug-spending-and-use-compare-across-large-employer-plans-medicare-part-d-and-medicaid/

[2] *See* Health Care Cost Institute, 2017 Health Care Cost and Utilization Report 14 (2019)https://www.healthcostinstitute.org/images/pdfs/HCCI_2017_%20Health_%20Care_Cost_and_Utilization_Report_02.12.19.pdf

[3] *See* Mercer's National Survey of Employer-Sponsored Health Plans, , Mercer (Oct. 28, 2019), https://www.mercer.com/newsroom/mercer-survey-finds-us-employers-shifting-to-innovative-strategies-to-make-healthcare-more-affordable-for-more-employees.html

There are a number of proposals pending in Congress to address prescription drug costs, including the House-passed Elijah E. Cummings Lower Drug Costs Now Act (H.R. 3), the Prescription Drug Pricing Reduction Act (S. 2543), approved by the Senate Finance Committee, the Lower Health Care Cost Act (S.1895), approved by the Senate Health, Education, Labor and Pensions Committee, and the Lower Costs, More Cures Act (H.R. 19).

Although H.R. 3 passed the House, it is clear that the Senate will take a different path. The Administration opposed passage of H.R. 3, yet "welcomes bipartisan efforts to enact legislation that provides additional prescription drug-cost relief for American families."[4] We therefore ask Congress to focus on bipartisan solutions that have a chance of being signed into law and can, indeed, lower drug costs now. The Council applauds the inclusion of the bipartisan CREATES Act in the appropriations package enacted at the end of 2019. The CREATES Act represents a first step in bringing greater competition to the prescription drug market and we urge Congress to build on this legislative success.

The Council also urges Congress to look behind the curtain of the prescription drug "price" paid by public and private payers and consumers to focus on costs of discovering, developing, marketing and delivering prescription drugs. Transparency efforts should include greater accountability for pharmacy benefit managers (PBMs) as well.

The status quo is unsustainable. Comprehensive reforms are needed to change the incentives that lead to higher list prices, increase competition among all the players in the pharmaceutical drug space and bring greater transparency to drug pricing. There is common ground to be found on meaningful prescription drug reform legislation. We look forward to working with Congress and the executive branch to bring the voice of employer plan sponsors to this all-important effort.

Our specific comments on legislative proposals and recommendations are set forth in the attached appendix. Thank you for considering these comments. If you have any questions or would like to discuss these comments further, please contact us at (202) 289-6700.

Sincerely,

Ilyse Schuman
Senior Vice President, Health Policy
ischuman@abcstaff.org

[4] https://www.whitehouse.gov/wp-content/uploads/2019/12/SAP_HR-3.pdf

APPENDIX

1. DRUG PRICE NEGOTIATION PROGRAM

Title I of H.R. 3 would require the Centers for Medicare & Medicaid Services (CMS) to "negotiate" maximum prices with manufacturers of certain prescription drugs that do not have generic competition. Prices for those drugs could not exceed 120% of the average price in certain other countries. Noncompliant manufacturers would be subject to an excise tax of up to 95% of the sales of those drugs. The negotiated prices must be offered under Medicare and Medicare Advantage and may also be offered under private health insurance unless the group health plan or insurer opts out.

The Congressional Budget Office (CBO) estimates a $448 billion savings to the Medicare program from Title I between 2023 (when the program takes effect) and 2029.[1] CBO estimates Title I would increase revenues by about $45 billion, primarily because the availability of lower drug prices would reduce the estimated cost of health insurance offered by employers. CBO also estimates a reduction in drug manufacturer revenues of between $500 billion and $1 trillion.

The Council commends the recognition of the risk of cost-shifting to employer plans evidenced by extending the availability of the negotiated price in Title I to the commercial market. This may be an attractive option for employer plan sponsors to consider. However, such guardrails against cost-shifting may not be fully effective and do not apply to other provisions of the legislation directed at public programs.

If H.R. 3 reduces drug manufacturer revenues by as much as *$1 trillion* over the next ten years, as the CBO anticipates, affected manufacturers would likely seek to recoup lost revenue elsewhere within the health care system – especially in those areas of the bill that only apply to Medicare and are not extended to the commercial market. For example, prices would likely increase for drugs that are not subject to mandatory negotiation or in the commercial market for those provisions that do not apply to the commercial market.

Our member companies are concerned that other countries are not paying an appropriate share of the necessary research and development to bring innovative drugs to the market, disproportionally placing this burden on U.S. businesses, consumers and taxpayers and believe that the burden for incentivizing new drug development should be spread more equitably. However, an international pricing index is problematic for

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[1] Congressional Budget Office, U.S. Congress, Letter on *Budgetary Effects of the Elijah Cummings Lower Drug Costs Now Act* (Dec. 10, 2019). https://www.cbo.gov/system/files/2019-12/hr3_complete.pdf

Congressional Budget Office, U.S. Congress, Letter on *Effects of Drug Price Negotiation Stemming From Title I of H.R. 3, the Lower Drug Costs Now Act of 2019, on Spending and Revenues Related to Part D of Medicare* (Oct. 11, 2019). https://www.cbo.gov/system/files/2019-10/hr3ltr.pdf

two reasons. First, basing the cost of drugs in the U.S. on those in other countries does not account for the more limited availability of new medicines abroad versus in this country. Second, it is also quite possible that manufacturers may seek to increase prices abroad (to the extent permissible under the laws of the respective foreign nation) in order to effectively increase the maximum limit on H.R. 3's fair market price for drugs sold in the United States. Since the fair market price under the legislation is tied to the price for the drug in certain international markets, any such action by manufacturers to raise prices in other countries would result in higher prices paid by consumers in this country. Congress and the Administration should consider other means to spread the cost of innovation globally more equitably (e.g. through trade policy).

Foreign government policies that restrict access to drugs make prices in other countries an incomplete comparator. However, policies in other countries to regulate prices could provide important insights for efforts in this country. In some countries, regulatory pricing systems are intended to reward innovative drugs that provide genuine breakthrough clinical benefits.[2] The German system, for example, has been characterized as making decisions based on clear empirical evidence of clinical benefits to patients. Despite the many complexities in defining and ultimately assessing value, our goal in this country should be both affordability and to pay wisely based on value.

It is important to consider how the legislation will impact overall plan costs within the typical pharmacy benefit manager (PBM) construct currently utilized by many employer-sponsored plans. It is very common for employer-sponsored plans to enter into a bundled pricing arrangement with a PBM wherein the PBM — anticipating rebates from drug manufacturers — agrees to provide discounted prices to the plan for the entire *bundle* of drugs on the plan's formulary. Therefore, although H.R. 3 permits employer plans to pay the negotiated price, it is very possible that for financially sound reasons, an employer plan sponsor may elect not do so with respect to a *specific* drug.

At the same time, employers acknowledge CBO's conclusion that the existing system of rebates and discounts does not easily facilitate those new transactions between manufacturers, pharmacies and plans stemming from the negotiated price proposal. One would therefore expect PBMs to seek to recoup any lost rebate revenues through other means. To protect employers – the largest purchasers of pharmaceuticals in the country – and the workers and families to whom they provide health coverage, the Council urges thorough consideration of the potential impact of H.R. 3 on employer plans

In the short term, CBO expects that lower prices would increase use of drugs and improve people's health. Indeed, CBO concludes that policy changes that increase Medicare beneficiaries' use of prescription drugs would reduce spending for other Medicare services by about $42 billion over the 2023-2029 period.

[2] https://www.healthaffairs.org/do/10.1377/hblog20161229.058150/full/

Over time, however, CBO estimates that the reduction in manufacturers' revenues would result in lower spending on research and development and thus reduce the introduction of new drugs. CBO predicts that H.R. 3 will reduce the number of new drugs coming to market by approximately eight drugs over the next 10 years. Because the development period for many drugs is longer than 10 years, estimating the impact on drug development only over the first 10 years that the proposed law would be in effect may underestimate the true future impact. Indeed, further CBO analysis estimates about 30 fewer drugs over the subsequent decade. The Food and Drug Administration approves, on average, about 30 new drugs annually, so the projected impact would be to reduce drug approval by about 10%. CBO acknowledges that it is difficult to know in advance the nature of these drugs or to quantify the effect of foregone innovation on health.

The Council applauds H.R. 3's recognition that fostering competition among manufacturers leads to reduced prices in the long run. Such competition has the potential to deliver significant benefits to payers in the marketplace, not only by improving the quality and efficacy of products, but also by spurring innovation in product design and delivery. However, it is not just the presence of generic drugs on the market that spurs competition. *Brand* competition also spurs competition in many classes of drugs, driving down costs. Therefore, basing price controls only on instances where there is no generic competition could have a harmful impact on competition. We encourage Congress to address situations where a complete lack of, or limited, competition – either from generic or brand drugs – for high cost, single-source drugs is currently limiting consumer access to these treatments and placing upward pressure on costs borne by employers and workers.

2. PROPOSED MEDICARE INFLATION REBATES

Both H.R. 3 and S. 2543 include provisions that would require manufacturers to pay a "rebate" to Medicare if the price of a drug rises faster than inflation. H.R. 3 would limit price increases for all drugs covered under Medicare Parts B and D by requiring manufacturers either to (1) reduce the prices of drugs as listed in January 2016, adjusted for inflation; or (2) issue a rebate in the amount of the difference between the current list price and the inflation-adjusted amount. In S. 2543, increases in price and inflation for existing drugs would be referenced to July 1, 2019.

While the Council supports efforts to keep seniors' drugs costs in check, the Council notes that the proposed inflation rebate only applies to Medicare. The Council is concerned that the contemplated inflation rebate to Medicare may shift costs to employer-sponsored plans. Consequently, the effects of the inflation rebate component could be disproportionately externalized on non-governmental program payers such as private employers (and their employees) in connection with employer-sponsored plans. CBO estimates that Title II of H.R. 3 would reduce Medicare spending by about $37

billion and increase federal revenue by about $500 million over the 2020-2029 period because of a reduction in the net price of some drugs in the commercial market (and the corresponding reduction in tax deductions related to drug spending). Additionally, since under the legislation negotiated prices apply, at any given time, only to drugs *already* on the market, purchasers could see a rise in the price of *new* drugs that are launched. The Council recognizes efforts to potentially extend inflation rebate provisions to drugs covered under group health plans as reflected in language included in the House-passed version of H.R. 3. The Council urges further consideration and evaluation of the inflation rebate component and, specifically, its potential effects on employer-sponsored plans.

Additionally, the Council also urges policymakers to focus not only on *price* but on *cost* as well. Both rebates and discounts are frequently driven off drug manufacturers' pricing models. The ability to focus instead on actual drug costs will help remove any dependency on linking rebates to inflation and will help address both the rebate and discount discussion. The Council also believes it is important to reinforce the distinct difference between rebates and discounts. We are concerned the terms are often used synonymously and we believe it is critical to ensure policymakers take into account the difference between the two and how they are applied. Discounts reduce the initial price paid at the pharmacy, while rebates are negotiated with brand manufacturers by PBMs to earn money back after drugs have been sold. Manufacturers pay rebates to earn access and to reward volume.

3. TRANSPARENCY

The Council urges Congress to focus on increased transparency regarding drug prices and drug *costs* as well and the entire ecosystem needed to deliver innovative medicines to patients. Many prescription medicines are high-value—they can cure diseases, lower other health care spending in the long run and keep employees healthier at home and more productive at work. Employers want to make sure they are spending resources wisely and, as the largest purchaser of prescription drugs in America, they have significant insight into the factors that shape drug costs. Increased availability of cost information, if properly designed and carefully implemented, could help consumers (including employer plan sponsors and their employees) make better informed and sensible purchasing decisions that result in higher-value pharmacy expenditures.

Increased transparency regarding drug manufacturers' unit costs might allow for more effective negotiations among private entities aimed at ensuring reasonable cost recovery and profits for manufacturers, while ensuring that plans, participants and the system as a whole are not overcharged for the drugs. We support provisions in H.R. 3, S. 2543 and S. 1895 that recognize the importance of transparency. The drug price transparency provisions in both H.R. 3 and S. 2543 would require drug manufacturers

to report to the Secretary of Health and Human Services (HHS) information and supporting documentation to justify price increases above certain thresholds for prescription drugs and biological products. The required information for the price justifications may include factors such as manufacturer spending for materials and manufacturing, patents and licenses, research and development and marketing and advertising. The price justification would be publicly posted, except that HHS would be prohibited from publicly posting any proprietary manufacturer information. These reports could be very useful to employers, although the burden associated with compliance might be significant.

Manufacturer price transparency alone does not provide a complete picture. Increased transparency throughout the pharmaceutical distribution system is needed. As a general matter, employers find the current rebate structure complex and opaque, hiding the true prices of drugs and the true value of how the rebate is calculated. While some PBMs may disclose the nature and extent of specific drug rebates, this practice varies by PBM. Moreover, when PBM compensation is tied to a percentage of the list price of the drug, this can create a market incentive that encourages higher list prices and larger rebates, specifically where the PBM compensation is factored into the cost of the drug by the drug manufacturer (and gets reflected in the list price set by the drug manufacturer). This can have a particularly negative impact on consumers enrolled in high deductible health plans that pay the list price of the drug rather than a lower price that reflects the rebate.

The Council supports provisions in S. 1895 that require greater transparency with respect to PBMs and the pass-through of rebates or discounts to plan sponsors. These provisions are of great importance to employer plan sponsors in their efforts to lower prescription drug costs. Specifically, S. 1895 would require that group health plan sponsors receive reports on the costs, fees and rebate information associated with the PBM contracts. Employers need access to information regarding the extent and nature of rebates paid to their PBM by drug manufacturers. The legislation would also require the PBM to pass on 100% of any rebates or discounts to the plan sponsor. The Council strongly urges Congress to include these provisions in a drug-pricing measure. The need for greater transparency by PBMs regarding the full extent of discount pricing, including (but not limited to) volume-based rebates, is essential.

4. MEDICARE PART D REDESIGN

Under current law, drug manufacturers pay 70% of the costs for Medicare Part D enrollees in the "coverage gap". When Medicare Part D enrollees' annual out-of-pocket spending exceeds the "catastrophic" coverage threshold, current law requires that enrollees pay the greater of 5% of their drug cost or a nominal set co-payment, plans pay 15% and Medicare pays 80%. The current allocation of costs in the catastrophic coverage phase in Medicare Part D has been criticized as a contributing factor to higher

prescription drug costs. The Council is encouraged by proposals in H.R. 3 and S. 2543 that would change the current allocation to ensure that drug manufacturers pay more of the cost for expensive drugs in the catastrophic coverage phase. Specifically, the proposals would create a new manufacturer discount program in the catastrophic coverage phase of the benefit and phase out the manufacturer discount program in the coverage gap. Accordingly, by increasing their exposure for high-cost drugs, manufacturers will be better incentivized to lower prescription drug costs.

5. INCREASING COMPETITION

The Council also supports policies to promote competition and prevent tactics that delay the availability of generic drugs in the market. To that end, the Council applauds enactment of the CREATES Act. We urge you to build on these efforts by including in drug pricing legislation additional provisions to improve competition; such as:

- The Bringing Low-cost Options and Competition while Keeping Incentives for New Generics (BLOCKING) Act (H.R. 938), preventing first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market.

- The Protecting Consumer Access to Generic Drugs Act (H.R. 1499), prohibiting "pay-for-delay" drug patent settlements between brand and generic drug manufacturers.

- The Purple Book Continuity Act (H.R. 1250), codifying publication of the patents of approved biological products in the Purple Book[3] in a similar format and with similar requirements to the Orange Book[4], specifying that the Purple Book should be published electronically on FDA's website and updated routinely, and directing FDA to consider the types of patents that should be listed in the Purple Book.

- The Orange Book Transparency Act (H.R. 1503), helping to ensure that the Orange Book is accurate and up-to-date by requiring manufacturers to share complete and timely information with FDA, as well as ensuring that patents listed in the Orange Book are relevant to the approved drug product. Patents found to be invalid through a court decision or a decision by the Patent Trial and Appeal Board would be required to be removed promptly.

[3] The FDA's "Purple Book" lists biological products, including any biosimilar and interchangeable biological products, licensed by FDA under the Public Health Service Act (the PHS Act).

[4] The publication Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book) identifies drug products approved on the basis of safety and effectiveness by FDA under the Federal Food, Drug, and Cosmetic Act and related patent and exclusivity information.

- Ensuring that drug manufacturers cannot receive new chemical entity exclusivity (NCE) for making small modifications to old drugs – and that only the most innovative or novel drugs qualify for exclusivity.

6. CHRONIC DISEASE MANAGEMENT ACT

The Council also urges Congress to pass the bipartisan Chronic Disease Management Act (S. 1948/H.R. 3709) that will lower out-of-pocket costs for millions of employees with chronic conditions by allowing health savings account-eligible high-deductible health plans to cover chronic disease prevention and treatment on a pre-deductible basis.

CONCLUSION

We believe the careful congressional consideration of the above-referenced matters will help achieve a meaningful response to drug pricing, while protecting both manufacturer innovation and employer-sponsored plans.