Subcommittee on Health of the
House Committee on Energy and Commerce

Hearing on: "Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans"

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Statement for the Record
Submitted by ASHP

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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Subcommittee on Health of the House Committee on Energy and Commerce (Subcommittee) hearing on "Making Prescription Drugs More Affordable: Legislation to Negotiate a Better Deal for Americans."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

We applaud the Committee's efforts to address drug pricing. ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities.

Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase. According to a recent Kaiser Health Tracking Poll, 29% of adults report not taking their medications as prescribed due to increased cost and 8% say their condition has worsened as a result of poor medication adherence.[1]

ASHP has been proactively addressing challenges related to the rapid increase of prescription drug prices on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burden of drug costs faced by patients, healthcare providers, and the entire healthcare system.

ASHP is committed to continuing to advance policy and other solutions that will lower the costs of prescription drugs, promote open competition in the marketplace, and provide patients with the proper access to care. We look forward to bipartisan solutions to the drug pricing epidemic and are pleased that Congress has taken steps over the past few months to address the issue of rising drug costs in the country. We appreciate the opportunity to work with you and your colleagues on this issue.

ASHP supports the following provisions in the bill:

Title II: Medicare Part B and D Prescription Drug Inflation Rebates

ASHP is supportive of efforts to control the growth of prescription drug prices over time. We feel that the section concerning drug inflation rebates for Medicare Part B and D is a step in the right direction to achieve that goal. Generally, we favor the imposition of rebates when drug prices outpace inflation. However, because the legislation would impose the rebates retroactively to 2016, we would like clarification as to how the rebate payments will be used to

[1] Kirzinger, A., Lopes, L., Wu, B., & Brodie, M. (2019, March 15). KFF Health Tracking Poll – February 2019: Prescription Drugs. Retrieved March 8, 2019, from https://www.kff.org/health-costs/poll-finding/kff-health-tracking-poll-february-2019-prescription-drugs/

reduce beneficiary out-of-pocket costs and systemic costs. We were pleased to see that the draft includes an economic incentive for manufacturers to produce drugs in shortage by exempting them from this formula. Drug shortages contribute to price increases and pose a significant threat to patient care in hospitals and other settings. This can result in delayed treatment and increased risk to adverse reactions and medication errors. Shortages force healthcare providers to spend time and resources locating medications instead of focusing on direct patient care. We encourage the Committee to consider additional steps to reduce the frequency of drug shortages, including:

- Requiring manufacturers to provide the Food and Drug Administration (FDA) with more information on drug shortages and their expected durations and allow public reporting of this information.
- Requiring manufacturers to disclose manufacturing sites, including the use of contract manufacturers, and sources of active pharmaceutical ingredients (APIs) to FDA.
- Requiring manufacturers to establish contingency plans to maintain the supply of a drug in the event of a manufacturing disruption.

Title III: Part D Improvements and Maximum Out-of-Pocket Caps for Medicare Beneficiaries

ASHP supports proposals which will lower the cost of drugs for patients and believes that the approach proposed in this section is an important step to protect patients from the high cost of drugs. Setting out-of-pocket limits for seniors will greatly reduce the burden they face from rising drug costs.

Additional Considerations

We appreciate the Committee's focus on addressing the very important issue of rising drug costs for patients and consumers. We also encourage the Committee to address the following policies in this legislation:

Increase Generic Competition

Drug manufacturers have abused the patent system and safety requirements to prevent competitors from entering the generic marketplace. Manufacturers should be barred from using tactics like "pay for delay" and be required to justify price increases. We support legislation which has received bipartisan support in both the House and Senate, such as the

- The FAIR Drug Pricing Act of 2019 (H.R. 2296, S.1391), which requires drug manufacturers to report publicly and provide justification for price increases.
- The Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019 (H.R. 965, S. 340), which prohibits manufacturers from using safety requirements to prevent generic competitors from accessing samples of brand named products.
- The Protecting Consumer Access to Generic Drugs Act of 2019 (H.R. 1499), which prohibits paying generic competitors from entering the marketplace.
- The REMEDY Act of 2019 (H.R. 3812, S.1209), which prohibits the unfair extension of patents to maintain market exclusivity.

Prevent PBMs from Imposing Retroactive DIR Fees

Direct and Indirect Remuneration Fees (DIR Fees) reform is a longstanding ASHP priority. DIR fees, which are negotiated by pharmacy benefit managers (PBMs), make it difficult to determine the actual cost of a drug. DIR fees are a nationwide concern for community pharmacies and outpatient clinics alike.

In many cases, DIR fees are not calculated until the drug is dispensed and the claim adjudicated. Moreover, the fees themselves, which are often arbitrary in nature, have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals in the tens of thousands to hundreds of thousands of dollars. Due to the fee structure, DIR fees assessed on pharmacies providing specialty medications have been especially problematic. Fees range from a flat rate of per dollar per claim or a percentage (typically 3%–9%) of the total reimbursement per claim. Additionally, these fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment.

DIR fees have resulted in higher cost-sharing responsibilities for Medicare beneficiaries. This has, in turn, caused more of these beneficiaries to enter the Part D donut hole where the patient is solely responsible for the cost of the drug. Along with the higher costs absorbed by patients, adherence rates tend to be lower among Medicare beneficiaries who are in the donut hole and may not have the financial resources to pay for their medications. These increased patient costs stand in stark contrast to the original intent behind imposing DIR fees targeting manufacturer rebates — passing on savings to patients.

We ask that you consider incorporating DIR reform language in your proposal. In the interim, we ask that you consider supporting legislation such as the bipartisan Phair Relief Act of 2019 (S. 2247), which would put a 5-year freeze on DIR clawbacks and will establish enhanced oversight of these fees.

Reject CMS' Proposal to Reduce Reimbursement for 340B Hospitals

The 340B Drug Pricing program is essential to many hospitals ability to provide healthcare services, including access to medications for uninsured and underinsured patients. Undermining this program will jeopardize patient care without resulting in significant cost savings. It is vital that any drug pricing proposals include provisions which would ensure the viability of 340B hospitals and ensure that patient care is not adversely affected.

Conclusion

ASHP thanks Committee for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.