Subcommittee on Health
House Committee on Energy and Commerce

Hearing on: "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition"

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Statement for the Record
Submitted by ASHP

American Society of Health-System Pharmacists
4500 East West Highway, Suite 900
Bethesda, MD 20814
Email: gad@ashp.org
Phone: 301-664-8692

ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Subcommittee on Health, House Committee on Energy and Commerce hearing on "Lowering the Cost of Prescription Drugs: Reducing Barriers to Market Competition."

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.

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. According to a Kaiser Health Tracking Poll, 1 in 4 Americans cannot afford their medications.[1] Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase.

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

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals, health systems, and patient advocacy groups. CSRxP has developed a policy platform promoting market-based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower drug prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product.

ASHP, along with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), recently released a report on the impact that the cost of and access to prescription drugs are having on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal year (FY) 2015 and FY2017.
- Outpatient drug spending per admission increased by 28.7%, while inpatient drug spending per admission increased by 9.6% between FY2015 and FY2017.

[1] DiJulio, Bianca, et al. "Kaiser Health Tracking Poll: August 2015." The Henry J. Kaiser Family Foundation, The Henry J. Kaiser Family Foundation, 20 Aug. 2015, https://www.kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015/. Accessed February 10, 2019.

- Hospitals experienced price increases of over 80% across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in 4 hospitals had to cut staff to mitigate budget pressures.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from pharmacy leaders in hospitals and health systems that sudden, inexplicable, and unpredictable price increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent — and are occurring on a nationwide basis.

We appreciate the committee's consideration of legislation designed to increase competition. Improving generics competition could not only reduce out-of-pocket costs, but also significantly strengthen the medication supply chain. Specifically, in 2018, clinicians faced acute shortages of the most basic generic products necessary for almost all patient care, including sterile water, sodium bicarbonate, small-volume parenterals, and injectable opioids. Such shortages jeopardize patient safety and siphon clinician resources away from direct patient care to shortage management, resulting in significant systemic costs, including increased prices. As we have worked diligently to address the issue of drug shortages for nearly 15 years, we urge the committee to explore means to incentivize generic competition and manufacturing upgrades to reduce and eventually eliminate shortages.

Although drug shortages are caused by a number of factors, when drugs in short supply are produced by only one or two manufacturers, prices increase. Stimulating market presence could help temper these price spikes. Thus, ASHP urges the committee to look at ways to incentivize marketplace participation. ASHP supports two bills being considered today: H.R. 985, the Fair Access for Safe and Timely (FAST) Generics Act of 2019" and H.R. 1499, the "Protecting Consumer Access to Generic Drugs Act of 2019." We believe that both bills would potentially increase competition. H.R. 985 would amend the Federal Food, Drug, and Cosmetic Act to ensure that eligible generic and biosimilar developers have competitive access to reference products, which is necessary in the development of generic drugs and biosimilars. H.R. 1499 would prohibit companies from engaging in "pay-to-delay" tactics, which stifle generic and biosimilar entry into the market.

Finally, we note that, in some cases, Risk Evaluation and Mitigations Strategies (REMS) have been used to circumvent generics competition. ASHP recognizes that manufacturer-driven REMS are necessary to ensure the safe use of certain medications. However, REMS programs should never be used to artificially inflate drug prices, nor should they interfere with the professional practice of pharmacists, physicians, nurses, and other providers. We believe there are cases in which manufacturer-driven REMS programs that require restricted distribution directly impact pricing, thereby increasing costs, reducing patient access, and delaying treatment. There is also evidence to suggest that the use of restricted or limited distribution channels has resulted in the inability of a potential competitor to acquire enough of a drug to conduct the required testing to bring a generic competitor to market. For this reason, we support H.R. 965, the "Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act of 2019." This bipartisan bill will help ensure that brand-name pharmaceutical companies cannot manipulate regulatory rules to prevent competition, which is essential for patient access to affordable medications. Additionally, we recommend that Congress require the Food and Drug Administration (FDA) to

investigate the use of restricted distribution REMS as a means to artificially increase drug prices and limit access to critical medications. Restricting distribution of medications is often a means to push patients to a specific purchasing channel, which in some cases increases not only their out-of-pocket costs, but also systemic costs. Further, restricted distribution networks can complicate patient access to critical medications, potentially disrupting care.

CONCLUSION

ASHP thanks the Subcommittee on Health, House Committee on Energy and Commerce 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.