

House Judiciary Subcommittee on
Regulatory Reform, Commercial and Antitrust Law

Hearing on: “Antitrust Concerns and the FDA Approval Process”

July 27, 2017

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: 301-664-8710

ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the House Judiciary Subcommittee on Regulatory Reform, Commercial and Antitrust Law hearing on “Antitrust Concerns and the FDA Approval Process.”

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization’s more than 44,000 members include pharmacists, student pharmacists, and pharmacy technicians. For 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety. For more information about the wide array of ASHP activities and the many ways in which pharmacists advance healthcare, visit ASHP’s website, www.ashp.org, or its consumer website, www.SafeMedication.com.

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 and significant increases charged by pharmacy benefit managers (PBMs), is one of ASHP’s highest and longstanding public policy priorities. ASHP has been proactively addressing and tackling challenges related to drug pricing on

several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, our members, 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 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 has been participating in a series of stakeholder meetings with key members of Congress to explore legislative solutions to the problem. As is evident by this hearing, there is significant support in Congress to address the problem,

although the approaches are varied and range from importation to government-negotiated prices.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from our members that sudden, inexplicable 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. ASHP is pleased that the Senate HELP Committee is holding this hearing, and we are eager to learn more about why these price spikes are occurring and explore potential policy options and market-based solutions to prevent or minimize the likelihood of this occurring in the future.

COMPETITION

In particular, ASHP would like to learn more about the marketplace dynamics that could contribute to unsustainable drug prices, as we have worked diligently on the issue of drug shortages for well over a decade. Although drug shortages are caused by a number of factors, we have observed that drugs in short supply made by only one or two manufacturers often result in higher than normal prices for these drugs when they are available. If, for example, there is a lack of competition in the generic marketplace, we urge the committee to look at ways to stimulate

more marketplace presence. ASHP supports bills such as H.R. 749, the “Lower Drug Costs through Competition Act” of 2017, which would potentially increase competition by expediting reviews of a generic drugs where there are currently no generic alternatives.

RISK EVALATION AND MITIGATION STRATEGY (REMS)

ASHP recognizes that there may be limited circumstances in which constraints on the traditional drug supply system may be appropriate for reasons of patient safety, often implemented under a manufacturer-driven REMS. However, we believe that these requirements are not appropriate to artificially inflate drug prices, nor should they interfere with the professional practice of pharmacists and prescribers. We believe that there may be current cases in which a manufacturer-driven REMS using restricted distribution is causing higher prices for those drugs, having adverse effects on patient access, and delaying treatment. In some cases, there may be 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, ASHP, individually and as part of the CSRxP, support bills such as H.R. 2212 the “Creating and Restoring Equal Access to Equivalent Samples

(CREATES) Act of 2017.” We recommend that Congress require the Food and Drug Administration (FDA) to investigate restricted distribution under a REMS program as a potentially limiting factor in accessibility to critical medications.

CONCLUSION

ASHP applauds your commitment to combating anticompetitive behavior that blocks access to affordable generic drugs. Such practices put a financial strain on patients and drive up healthcare expenses for everyone. ASHP thanks the Committee for holding this important hearing, and we look forward to learning more about the causes and potential solutions to this issue. Additionally, ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.