Employers' Prescription for Affordable Drugs

The Honorable Patty Murray
Chair
HELP Committee
United States Senate
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
HELP Committee
United States Senate
Washington, DC 20510

The Honorable Frank Pallone
Chairman
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
Washington, DC 20515

May 20, 2022

Dear Chairs Murray and Pallone, Senator Burr, and Congresswoman McMorris Rodgers:

As your committees continue consideration of legislation to reauthorize user fees funding the Food and Drug Administration (FDA)[1], I would like to offer the perspective of the nation's leading employers and health care purchasers. I write on behalf of the Employers Prescription for Affordable Drugs (EmployersRx), a coalition of leading national organizations representing large employers and health care purchasers across all fifty states. Built on the tenets of transparency, competition, and value, EmployersRx supports public policies that drive down the cost of drugs while preserving true innovation as part of a value-based health care system.

Eliminate Anti-competitive Patent Practices by Drug Makers

While the User Fee Acts are focused on funding the FDA and updating its approvals processes, Congress would be remiss not to take the opportunity to also rein in abuses regarding patent and market exclusivity processes. EmployersRx strongly supports a set of common-sense and to-date bipartisan proposals to reduce the cost of drugs by banning anticompetitive practices and enhancing price transparency. To that end, we urge policymakers to:

- Eliminate "patent evergreening" and other "patent thickets" to ensure that branded products will face competition from generic drugs and biosimilars in line with the intent of current laws.
- Prevent first-to-file generic drug applicants from blocking, beyond a 180-day exclusivity period, the entrance of subsequent generic drugs to the market.

[1] Prescription Drug User Fee Act of 2022 (PDUFA), Biosimilar User Fee Act of 2022 (BsUFA), and Generic Drug User Fee Act of 2022 (GDUFA)

- Reduce citizens petition abuse by giving the FDA additional guidance on denying petitions submitted for the purpose of delaying generic approval.
- Require drug manufacturers to publicly report and explain price increases that exceed certain thresholds.
- Require branded biologic companies to publicly list drug patents they can reasonably defend.
- Require health care providers and pharmacies to include National Drug Codes (NDC) in claims for commercial health plans. NDC codes are currently required for claims to public payers (Medicare and Medicaid) and provide greater transparency on prices to purchasers.

Hold PBMs and other Third Parties Accountable to Purchasers and Consumers

While Congress can take major steps to invigorate drug competition those reforms will have limited effect if not paired with fundamental reform to the opaque drug supply chain and distorted incentives that result in higher cost. Congress should take a fresh look at the drug supply chain and seek to both provide sunlight to complicated web of organizations in the supply chain and to hold all players, including PBMs, consultants and other third parties accountable. In particular, EmployersRx recommends that Congress:

- Require complete transparency by PBMs and other third parties. Transparency requirements should require prescription drug suppliers to disclose detailed pricing information on rebates, administrative fees, any other transactional fees when the supplier relies on any third parties between the pharmaceutical manufacturer and ultimately the delivery of medications to the patient. These transparency requirements should extend to contracted suppliers and in particular, any subsidiary corporations in which there may be a mutual or indirect ownership interest, including corporate entities headquartered outside the United States.
- Address spread pricing by PBMs, health plans, providers, and other intermediaries. Purchasers should be given the option to accept or reject spread pricing. This policy should apply to drugs administered directly by providers as well as those sold in the pharmacy setting.
- Establish a clear federal structure to regulate and oversee PBMs and their affiliates. Currently, a lack of clear federal regulatory authority over PBMs has led policymakers to seek to regulate the industry indirectly through placing additional regulatory burden on health plan sponsors (i.e., employers and purchasers).

America's employers and private health care purchasers provide health coverage to more than half the people in the United States and collectively spend tens of billions of dollars per year on prescription drugs. We appreciate your consideration of our views as you move forward with reauthorization of the FDA user fees and look forward to working together on this and other prescription drug priorities in the year ahead.

Employers' Prescription
for Affordable Drugs

Sincerely,

William E. Kramer
Executive Director for Health Policy
Purchaser Business Group on Health