

May 23, 2024

The Honorable Bernie Sanders
Chairman, Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Bill Cassidy
Ranking Member, Committee on Health, Education,
Labor and Pensions
United States Senate
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Chairwoman, Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20510

The Honorable Frank Pallone
Ranking Member, Committee on Energy & Commerce
United States House of Representatives
Washington, DC 20510

Dear Chairs Sanders and McMorris Rodgers and Ranking Members Cassidy and Pallone:

As your Committees continue to advance policies that expand access to affordable medicines, we write to express our strong support for the inclusion of bipartisan, bicameral legislation introduced by Senators Hassan (D-NH) and Braun (R-IN) and Representatives Kuster (D-NH) and Harshbarger (R-TN), the *Medication Affordability and Patent Integrity Act* (S. 2780 and H.R. 5429).

On behalf of the patients, consumers, and taxpayers we represent, we request the Committees take swift action to advance this legislation. It addresses a loophole often used by brand pharmaceutical companies to inappropriately extend market monopolies.

Currently, information gaps between the Food and Drug Administration (FDA) and U.S. Patent and Trademark Office (USPTO) enable brand companies to withhold important details about their principal patent from regulators until submitting subsequent ancillary patents much later in the process. What results is a system of artificially extended patent terms where brand drug companies assert “newness” on one hand to obtain a patent from USPTO, while maintaining “oldness” on the other hand to receive safety and efficacy approval from FDA.

American patent law relies on carefully constructed balance: a tradeoff between temporary exclusivity rights and subsequent open market competition, resulting in lower prices for consumers. This dynamic is upset when actors fail to timely disclose relevant information in order to artificially extend patent expiry and delay low-cost generic competition. The lapse in time between expiration dates of the principal and ancillary patents translates to a significant—and unnecessary—cost burden to patients and the healthcare system by delaying the approval and accessibility of low-cost generic medicines.

We support the following commonsense provisions in this legislation that will bring transparency to drug filings between FDA and USPTO, better inform agency decisions, and bolster timely competition that meaningfully increases patient access: 1) require manufacturers to certify that they have not made inconsistent statements to FDA and USPTO; and 2) create a new defense to infringement of a drug based on failure to comply. These simple solutions have received bipartisan support in both the House and Senate and will lower out-of-pocket costs for patients.

We stand ready to work with you and your Committee colleagues to strengthen transparency, promote competition, and enact bipartisan policy reforms that deliver meaningful savings to beneficiaries at the pharmacy counter.

Sincerely,

Allergy & Asthma Network
Alliance for Community Health Plans
American Society of Health-System Pharmacists
Asthma and Allergy Foundation of America
Bonnell Foundation
Boomer Esiason Foundation
CanDo Multiple Sclerosis
Cystic Fibrosis Research Institute
Emily's Entourage
Generation Patient
HealthyWomen
Lupus and Allied Diseases Association, Inc.
MS Views & News
Multiple Sclerosis Association of America
Multiple Sclerosis Foundation
National Multiple Sclerosis Society
Patients Rising
Rock CF Foundation