

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 Diabetes Association  
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