

November 18, 2022

The Honorable Chuck Schumer  
Majority Leader  
United States Senate  
Washington, DC 20510

The Honorable Mitch McConnell  
Republican Leader  
United States Senate  
Washington, DC 20510

The Honorable Nancy Pelosi  
Speaker  
United States House of Representatives  
Washington, DC 20515

The Honorable Kevin McCarthy  
Republican Leader  
United States House of Representatives  
Washington, DC 20515

Dear Leader Schumer, Leader McConnell, Speaker Pelosi, and Leader McCarthy:

On behalf of the patients, consumers, and taxpayers we represent, the undersigned organizations urge you to include policies that will increase patient access to affordable medicines in Congress' year-end Omnibus appropriations package. Specifically, we write to express our strong support for two bipartisan bills, the *Increasing Transparency in Generic Drug Applications Act* (S. 4338/H.R. 7032) and the *Enhanced Access to Affordable Medicines Act* (S. 4351/H.R. 6973), which will dramatically lower patient out-of-pocket costs and improve access to generic medicines. These bills were included with overwhelming bipartisan support in both User Fee Reauthorization packages passed by the Senate Health, Education, Labor, and Pensions (HELP) and House Energy and Commerce Committees and would facilitate more timely approval of and access to complex generic drugs. Striking the right balance between innovation and access is the hallmark of our drug approval system. Getting affordable medicines to market in an efficient, streamlined manner helps maintain that balance and ultimately will result in lower drug prices for Americans.

The *Increasing Transparency in Generic Drug Applications Act* addresses how the Food and Drug Administration (FDA) provides feedback to generic drug manufacturers seeking approval for complex generic drugs. Certain complex generic drugs are required to be quantitatively and qualitatively equivalent to the reference listed drug. Prior to 2015, FDA would provide feedback to generic drug applicants about whether their drug met these requirements, and if not, which ingredient(s) deviated from the reference listed drug and their direction (e.g., too high or too low). However, FDA abruptly changed this practice in 2015 and the Agency no longer provides either the ingredient(s) at issue or the general direction of the deviation. This lack of feedback has unnecessarily prolonged the application and approval process and significantly delayed patient access to these lower-cost treatments, often far beyond the time period envisioned by Hatch-Waxman.

The *Enhanced Access to Affordable Medicines Act* would also eliminate unnecessary delays in patient access to more affordable medicines by creating parity in label change requirements between brand and generic drugs. Prescriber information labels on generic drugs are required to be the same as the reference listed drug in order to be approved. This requirement has created a loophole that incentivizes companies to submit last minute label changes that delay generic drug approval. The *Enhanced Access to Affordable Medicines Act* would eliminate this loophole in the existing statutory provision and prevent last minute labeling changes from further delaying timely generic entry.

As you know, generics and biosimilars provide vast savings for patients and the healthcare system. Generics and biosimilars saved the U.S. \$373 billion in 2021 alone and have saved more than \$2.6 trillion over the past decade. However, delays in timely FDA approval of these lower-cost drugs puts those savings at risk. These commonsense, bipartisan, bicameral policies will help maintain the important balance between innovation and access, enable FDA to ensure timely review of lower-cost generic medicines, and reduce beneficiaries' out-of-pocket spending on prescription drugs. The undersigned organizations urge you to include these policies in the forthcoming Omnibus appropriations package to realize our shared goal of improving patients' access to affordable medicines.

Sincerely,

Allergy Asthma Network  
American Cancer Society Cancer Action Network  
American Diabetes Association  
Arthritis Foundation  
Asthma and Allergy Foundation of America  
Autoimmune Association  
Avery's Hope  
The Blue Hat Foundation, Inc  
Boomer Esiason Foundation  
Bonnell Foundation  
Center for Medicine in the Public Interest  
Children With Diabetes  
Colon Cancer Coalition  
Color of Crohn's & Chronic Illness  
Cystic Fibrosis Research Institute  
Diabetes Leadership Council  
The Diabetes Link  
Diabetes Patient Advocacy Coalition  
Diabetes Sisters  
International Foundation for Autoimmune & Autoinflammatory Arthritis  
National Multiple Sclerosis Society  
National Psoriasis Foundation  
Patients Rising Now  
RetireSafe  
Rock CF  
ZERO - The End of Prostate Cancer

cc:

*The Honorable Patty Murray*  
*The Honorable Richard Burr*  
*The Honorable Frank Pallone*  
*The Honorable Cathy McMorris Rodgers*