December 5, 2022

The Honorable Patty Murray
Chairwoman
U.S. Senate Committee on
Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Richard Burr
Ranking Member
U.S. Senate Committee on
Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Frank Pallone
Chairman
U.S. House Committee On Energy and
Commerce
2152 Rayburn House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
Ranking Member
U.S. House Committee on Energy and
Commerce
2152 Rayburn House Office Building
Washington, DC 20515

Dear Chairwoman Murray, Ranking Member Burr, Chairman Pallone, and Ranking Member McMorris Rodgers,

As Congress works toward finalizing an end-of-year budget package, we urge the chambers to include bipartisan legislation to address abuse of the Food and Drug Administration's (FDA) citizen petition process in order to reduce drug prices and save the government hundreds of millions of dollars by speeding generics to market to increase competition. The *Ensuring Timely Access to Generics Act* (S.562), sponsored by Sens. Shaheen (D-NH), Cassidy (R-LA), Bennet (D-CO), and Rubio (R-FL), strengthens the FDA's ability to reject citizen petitions if it believes the primary purpose of the petition is to delay approval of a generic competitor. CBO reports the reform will **save the government $207 million over ten years.** Sen. Baldwin (D-WI) offered the legislation as an amendment during the Senate HELP Committee's mark-up of the FDA user fee reauthorization legislation; it passed with a strong, bipartisan 16-6 vote.

The citizen petition process at the FDA is intended to provide a forum for patients, consumer groups, and other entities to raise safety concerns about FDA decision making, including drug approvals. Too often, however, this process is co-opted by brand-name drug companies to delay competition. Currently, the FDA must delay authorization of any drug in order to process all citizen petitions. Brand drug companies often game the system by raising invalid, outdated, or extraneous issues in order to block or slow competition from generic products that are poised to enter the market. To that point, research has revealed that brand-name drug makers were behind 92% of all 505(q) citizen petitions filed between 2011 and 2015. Overwhelmingly, these petitions were "shams," not raising legitimate safety concerns, which is why the FDA threw out nine of every 10 of these petitions.

Both the Trump and Biden administrations have identified submission of sham citizen petitions as a threat to timely approval of generics and competition. In 2018, Former FDA Commissioner Scott Gottlieb noted that manipulation of the process "can add to resource burdens on the generic drug review process and the FDA's regulatory decision making" and decrease the speed of the approval process. In its 2021 drug pricing competition plan, the Biden administration also said that legislative changes were needed to "make it harder for brand manufacturers to abuse the regulatory process to prevent the introduction of biosimilar and generic products" such as through manipulation of the citizen petition process.

In order to restore the intended purpose of the citizen petition process and ensure timely market entry of competition, we urge you to include the bipartisan *Ensuring Timely Access to Generics Act* in the year-end fiscal package.

Sincerely,

Patients For Affordable Drugs Now
Alliance of Community Health Plans
American College of Physicians
American Society of Health-System Pharmacists
Blue Cross Blue Shield Association
The Campaign for Sustainable Rx Pricing
Friends of Cancer Research
Protect Our Care

CC: Leader Schumer, Speaker Pelosi, Minority Leader McConnell, and Minority Leader McCarthy