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

Re: Support for inclusion of the "Enhanced Access to Affordable Medicines Act of 2022" (S. 4351/H.R. 6973) in the Fiscal Year 2023 Consolidated Appropriations Act

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

On behalf of the Generics Access Project (GAP), I am writing in support of the inclusion of S. 4351/H.R. 6973, the "Enhanced Access to Affordable Medicines Act of 2022" in the 2023 Consolidated Appropriations Act. This legislation will help to increase patient access to important generic medicines by decreasing any unnecessary delays to these medications reaching the market.

GAP is a coalition of patient advocacy groups who advocate for policies that promote generic competition and efficient approval of generic medicines. Generic medicines are a critical cost-lowering mechanism for patients and the healthcare system, and ensuring that patients have timely access to these important medications is crucial.

Generic drugs have become an incredibly important part of the U.S. healthcare system, with nearly 90% of all U.S. prescription volume being made up by generics, but accounting for only 22% of the total prescription drug spending[1]. The savings to the U.S. healthcare system as a result of increased access to generic drugs totaled $313 billion in 2019 alone[2].

The passage of S. 4351 (H.R. 6973) can help to ensure the timely approval of generic medications, and reduce the delay in patient access to generics. Generic drug labels are required to be the same as that of the reference product in order for an abbreviated new drug application (ANDA) to be approved. If the label is changed for the reference product shortly before the approval of the generic medication, the generic approval is delayed until the ANDA is amended with updated labeling matching the new reference label. This can lead to approval delays as long as three months, further delaying patient access to these important medications.

[1] IQVIA. (2019). Fact Sheet: Generic Drug and Biosimilar Access and Savings in the U.S. Report. https://accessiblemeds.org/sites/default/files/2019-12/AAM-2019-Generic-Biosimilar-Access-Savings-US-One-Pager.pdf
[2] The Association for Accessible Medicines, (October 2020) 2020 Generic Drug & Biosimilars Access & Savings in the U.S. Report https://accessiblemeds.org/sites/default/files/2020-09/AAM-2020-Generics-Biosimilars-Access-SavingsReport-US-Web.pdf

The improvements to current policy proposed in the "Enhanced Access to Affordable Medicines Act of 2022" could have a significant impact on both patient access and savings for the healthcare system. We urge you to include this policy in the coming omnibus appropriations package.

Thank you for the opportunity to share our comments in support of the important role generics play to lower costs for American patients. Should you have any questions, please contact Gavin Clingham at gavin@allianceforpatientaccess.org.

Sincerely,

Generics Access Project