



September 30, 2016

The Honorable Peter Welch
U.S. House of Representatives
2303 Rayburn House Office Building
Washington, DC 20515

The Honorable Morgan Griffith
U.S. House of Representatives
1108 Longworth House Office Building
Washington, DC 20515

Dear Representatives Welch and Griffith:

On behalf of ASHP (American Society of Health-System Pharmacists), I am writing in support of H.R 6174, the Closing Loopholes for Orphan Drugs Act. ASHP applauds your leadership on this issue.

ASHP is the national professional organization whose more than 43,000 members include pharmacists, pharmacy technicians, and student pharmacists who provide patient care services in hospitals, health systems, and ambulatory clinics. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

The Affordable Care Act (ACA) added a number of newly covered entities to the 340B Drug Pricing Program but stated that these entities could not purchase orphan drugs under the federal 340B program when those drugs were intended to treat the orphan indication. While an orphan status designation by the FDA indicates that the drug has been found “promising” for treating a rare disease, it does not mean that the drug is currently marketed solely for that indication in the United States. Many drugs receive an orphan status designation, but do not obtain marketing approval for that indication. These drugs, however, may be approved or otherwise legally used for other indications that do not meet the requirements of orphan status. Current interpretation of the orphan drug exclusion policy prevents eligible entities added under the ACA from purchasing medically necessary drugs at the 340B price. This bill would allow those entities currently subject to the orphan drug exclusion to purchase orphan drugs through the federal 340B program when the drugs are used to treat an illness other than the orphan indication. We believe that this bill is consistent with the congressional intent of the federal 340B program at the time of enactment, which is “to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

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ASHP thanks you for introducing this important legislation, and we look forward to working with you to move the bill forward. Please contact me with any questions or have a member of your team contact Christopher Topoleski, Director of Federal Legislative Affairs at 301-664-8806 or at ctopoleski@ashp.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Kasey K. Thompson', is written over a horizontal line. The signature is stylized and somewhat cursive.

Kasey K. Thompson, Pharm.D., M.S., M.B.A.
Chief Operating Officer and Senior Vice President