

December 13, 2017

Hon. Orrin Hatch
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, D.C. 20510

Hon. Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, D.C. 20510

Hon. Greg Walden
Chairman
House Energy & Commerce Committee
2125 Rayburn House Office Building
Washington, D.C. 20515

Hon. Frank Pallone
Ranking Member
House Energy & Commerce Committee
2322A Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Hatch, Chairman Walden, Ranking Member Wyden, and Ranking Member Pallone:

Thank you for your commitment to ensuring patient access to safe, effective and affordable medicines. We, the undersigned, support the development of a robust and sustainable market for FDA-approved biosimilars in the United States for patients and consumers seeking safe and effective treatments. Biosimilars hold great promise for patients and would improve the sustainability of our health care system. To achieve that promise, we write to you today to raise to your attention a significant unintended barrier to biosimilar utilization and request your assistance in advancing a legislative solution to lower prescription drug costs for millions of patients, seniors and individuals with disabilities in Medicare.

In 2010, Congress created the Coverage Gap Discount Program to limit patient out-of-pocket costs in the Medicare Part D prescription drug program. Medicare Part D requires brand-name manufacturers to provide discounts of 50 percent to patients in the coverage gap. For 2017, the coverage gap under the standard benefit is from \$3,700 to more than \$8,000 in total drug costs. Moreover, these discounts are used in the calculation of True Out of Pocket (TrOOP) and critical to determining when a beneficiary enters the catastrophic phase of coverage.

However, as a result of a legislative oversight, biosimilar manufacturers are not eligible to pay those discounts, leaving patients and Part D plans to pick up the cost differential. This incentivizes Part D plan sponsors to place patients on higher-cost brand biologics and leads to patients paying higher out-of-pocket costs for what are otherwise more affordable biosimilars. A 2016 Avalere study noted that for a sample drug that costs \$30,000 per year, patient costs for a biosimilar would, at the time, be over \$1,500 more per year (39 percent higher) than the brand product.¹ Current law thus creates a significant barrier for prescription drug manufacturers to develop biosimilars as it would be difficult to offer sufficient discounts to effectively compete and be covered under the Medicare Part D program.

¹ Patient Out-of-Pocket Costs for Biosimilars in Medicare Part D. Avalere Health. April 2016. ([link](#))

We encourage Congress to enact legislation to classify biosimilars as “applicable drugs” in the Coverage Gap Discount Program. This small change would require biosimilar manufacturers to pay the 50 percent discounts paid by their brand competitors, creating a level playing field to compete for placement on Part D plan formularies. Enabling biosimilar manufacturers to pay the discount would reduce both patient out-of-pocket costs and Part D program spending and provide the federal government with at least \$1 billion in savings over ten years.²

Thank you for your time and consideration of this change to the Coverage Gap Discount Program. We look forward to working with you to lower prescription drug costs for millions of Medicare beneficiaries.

Sincerely,

Academy of Integrative Pain Management
Allergy & Asthma Network
American Brain Tumor Association
American Cancer Society Cancer Action Network
American Consumer Institute
American Sustainable Business Council
Black Women’s Health Imperative
Bladder Cancer Advocacy Network
Caregiver Action Network
Coalition to Reduce Spending
Consumer Action
The Council for Citizens Against Government Waste
FORCE: Facing Our Risk of Cancer Empowered
FreedomWorks
Frontiers of Freedom
Global Healthy Living Foundation
Independent Women's Voice
Leukemia & Lymphoma Society
Mended Hearts
National Alliance on Mental Illness
National Consumers League
National Hispanic Medical Association
National Medical Association
National Patient Advocate Foundation
Prevent Cancer Foundation
U.S. Pain Foundation

cc: Senate HELP Committee
House Ways & Means Committee

² “Biosimilar Inclusion in Manufacturer Coverage Gap Discount Program: Fiscal Implications.” The Moran Company. October 2017. ([link](#))