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Two Woodfield Lake
1100 E Woodfield Road, Suite 350
Schaumburg, IL 60173-5116
P: (847) 517-7225 | F: (847) 517-7229
Email: csro@wjweiser.com | Website: www.csro.info

March 15, 2018

The Honorable Paul Ryan
Speaker,
U.S. House of Representatives
Washington, DC 20515

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

The Honorable Nancy Pelosi
Minority Leader,
U.S. House of Representatives
Washington, DC 20515

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

Speaker Ryan and Leaders McConnell, Schumer, and Pelosi:

The undersigned organizations write to urge inclusion of biosimilar payment equality in the 2018 funding package. As explained below, we believe this would benefit patients by reducing out-of-pocket costs, avoid creating an incentive for non-medical switching of medication, and result in savings for the Medicare program.

When Congress created a regulatory pathway for approval of biosimilars by the Food and Drug Administration, it established the same reimbursement for reference products and biosimilars. Both kinds of products would be reimbursed at the reference product's average sales price (ASP) plus 6%. However, the Hospital Outpatient Prospective Payment System (HOPPS) for calendar year 2018 released by the Centers for Medicare and Medicaid Services would upset this balance. For drugs purchased pursuant to the 340B program, reimbursement would drop from ASP plus 6% to ASP minus 22.5%, but biosimilars eligible for "transitional pass-through payment" are exempted from this change. This has the effect of allowing continued reimbursement for newly marketed biosimilars at ASP +6% of its reference product, while that same reference product or an older biosimilar of that same reference product may be reimbursed at ASP –22.5%.

We believe that this stark differentiation between reimbursement for new biosimilars and reference products runs counter to congressional intent, as Congress expressly provided in statute that biosimilars and reference products should be subject to the same reimbursement paradigm. Additionally, this would create a counterintuitive situation in which patients may have higher out-of-pocket costs if they are switched to the biosimilar, because coinsurance percentages would be based on the cost of a product that is reimbursed at a much higher level than the reference product. Such switches would be frequent, as the higher reimbursement for new biosimilars would create a strong incentive for hospitals to switch patients to those biosimilar products, even when the patient's condition is medically stable and there is no clinical reason to make the switch. Finally, the Congressional Budget Office indicated that including new biosimilars in the changes made by the HOPPS would save the government $392 million over ten years.[1]

In light of the above concerns, we urge you to include a provision in the spending package that would return equity to reimbursement between reference products and biosimilars purchased pursuant to 340B.

[1] https://cbo.gov/system/files/115th-congress-2017-2018/costestimate/divisionfhousecr.pdf, page 4 of 5, see line item "Sec. 2709. Transitional pass-through payment change for certain products."

Thank you for your consideration. Should you have any questions, please contact Judith Gorsuch, jgorsuch@hhs.com.

Respectfully submitted,

Michael P. Stevens, MD, FACR
President
Coalition of State Rheumatology Organizations