December 4, 2024

The Honorable Mike Johnson
Speaker
U.S. House of Representatives
H-232, The Capitol
Washington, DC 20515

The Honorable Charles Schumer
Majority Leader
U.S. Senate
S-221, The Capitol
Washington, DC 20515

The Honorable Hakeem Jeffries
Minority Leader
U.S. House of Representatives
H-204, The Capitol
Washington, DC 20515

The Honorable Mitch McConnell
Minority Leader
U.S. Senate
S-230, The Capitol
Washington, DC 20515

RE: The Biosimilar Red Tape Elimination Act (S.2305)

Dear Speaker Johnson, Majority Leader Schumer, Minority Leader McConnell, and Minority Leader Jeffries:

The undersigned organizations of the Underwater Biosimilars Coalition ("The Coalition") are committed to improving access to provider-administered (Medicare Part B) medications, including biosimilars. The Coalition is comprised of over 40 organizations, representing a broad range of providers and patient advocates nationwide. While the Biosimilar Red Tape Elimination Act (S.2305) aims to improve access to biosimilars, the undersigned organizations are concerned that this bill fails to recognize an immediate serious barrier to patient access to provider administered biosimilars – "underwater" provider reimbursement. Without addressing this inadequate, or "underwater" reimbursement, patients will continue to lose access to needed biosimilars and their reference product (i.e., brand biologics) and biosimilar adoption will continue to hit roadblocks. This situation may only worsen as more provider – administered biosimilars come to market.

Reference biologics and biosimilars are vitally important therapeutic options for patients with certain chronic diseases, including cancer, immune related diseases, inflammatory bowel disease, rheumatoid/psoriatic arthritis, multiple sclerosis, and macular degeneration. In addition to reducing pain and dysfunction related to these conditions, these medications reduce the frequency of costly downstream disease-related complications, including cardiovascular diseases, steroid related side effects, increased hospitalizations, expensive procedures and surgeries. Biosimilars currently undergo rigorous testing to demonstrate comparable safety and efficacy to their reference products and can provide a lower cost alternative to the reference biologic to help with specialty medication affordability in the United States.

Health insurers and their pharmacy benefit managers (PBMs) pressure pharmaceutical manufacturers to offer significant rebates in exchange for "fail first" status on their formularies. In this situation, certain highly rebated biosimilars have gained the "fail first" position, requiring patients to step through these medications before they can access others. Interestingly, commercial plans, including Medicare Advantage plans, pay no attention to the "interchangeability' of the biosimilar when constructing formularies, only to the size of the rebates and fees collected.

In contrast to self-administered medications, provider administered medication rebates are reflected in manufacturers' quarterly ASP reporting to the Centers for Medicare and Medicaid Services (CMS).

Certain highly rebated provider administered biosimilars have *artificially* significantly lowered the ASP to the point that many providers' acquisition costs substantially exceed Medicare, Medicare Advantage and other private health plan reimbursements for these medications. This issue has been brewing over the last two years and continues to grow. While Congress increased the ASP "add-on" for select biosimilar medications through the Inflation Reduction Act for a limited five-year period, physicians are still underwater with these highly rebated biosimilars because the ASP is so artificially low.

Many independent physician practices, as well as free-standing infusion suites, directly administer drugs to patients in outpatient facilities and typically engage in a practice known as "buy and bill." These practices pre-purchase drugs and bill the payer for reimbursement once the medication is administered to the patient. Margins for practices engaged in buy and bill are thin. To maintain the viability of administering drugs in this setting, reimbursement must account for overhead costs, such as intake and storage, equipment and preparation, staff, facilities, and spoilage insurance. These acquisition costs are typically accounted for within the average sales price (ASP) formula for physician administered drugs.

Unfortunately, the precipitous drop in ASP for certain biosimilars has led to inadequate, or "underwater," reimbursement, forcing providers into an untenable position. It is the "fail first" status of these "underwater" biosimilars in the Medicare Advantage and commercial plans forcing providers to use them first, that creates the untenable situation. Providers are faced with the choice to administer the drug at a financial loss – which is unsustainable, or switch the patient to an entirely different therapy. Transferring care to another site of service has become increasingly difficult as free-standing infusion suites and even some hospitals refuse to accept these patients due to underwater reimbursement. As a result, patients are losing access to the biosimilar medication that best treats their medical condition. For example, patients with inflammatory bowel disease are being admitted to the hospital for acute flares and to obtain their medication. **It should be noted that "straight" Medicare beneficiaries do not face this issue because those formularies, unlike Medicare Advantage, do not have these "fail first" policies.**

The Biosimilar Red Tape Elimination Act (S.2305) would hope to improve access to biosimilars by allowing biosimilars to be interchangeable with the reference product without the need for additional evidence from the manufacturer. While there may be disagreement on its ultimate value, the legislation most importantly fails to recognize and address these "underwater" barriers that are currently limiting access to approved biosimilars, whether or not they are interchangeable.

We urge Congress to address this provider "underwater" biosimilar issue, whether through increased reimbursement, recalculation of ASP, relaxing mandated "fail first" policies on unaffordable biosimilars, or any other viable options. The status quo on this issue will remain a significant obstacle to full biosimilar integration into the market and more importantly, an obstacle to patients' access to urgently needed medications.

The Coalition is dedicated to working with Congress on solutions that ensure all patients have access to high quality care and that all providers are reimbursed fairly for providing it. We look forward to partnering with you on this endeavor and serving as a resource to address "underwater" biosimilars. Please contact the Coalition of State Rheumatology Organizations at jfrasco@hhs.com if you have any questions.

Sincerely,

Alabama Society for the Rheumatic Diseases
Alaska Rheumatology Alliance
American College of Gastroenterology
American College of Rheumatology

American Gastroenterological Association
American Society for Gastrointestinal Endoscopy
Arizona United Rheumatology Alliance
Arkansas Rheumatology Association
Association of Women in Rheumatology
California Rheumatology Alliance
Chicago Rheumatism Society
Coalition of State Rheumatology Organizations
Colorado Rheumatology Association
Connecticut Rheumatology Association
Digestive Health Physicians Association
Florida Society of Rheumatology
Georgia Society of Rheumatology
Infusion Providers Alliance
Kentuckiana Rheumatology Alliance
Lupus and Allied Diseases Association, Inc.
Maryland Society for the Rheumatic Diseases
Massachusetts, Maine, and New Hampshire Rheumatology Association, Inc.
Michigan Rheumatism Society
MidWest Rheumatology Association
National Infusion Center Association
National Organization of Rheumatology Management
New York State Rheumatology Society
North Carolina Rheumatology Association
Ohio Association of Rheumatology
Rheumatology Alliance of Louisiana
Rheumatology Association of Minnesota and the Dakotas
Rheumatology Society of New Mexico
Southern California Rheumatology Society
Spondylitis Association of America
State of Texas Association of Rheumatologists
Tennessee Rheumatology Society
Virginia Society of Rheumatology
Washington State Rheumatology Alliance
West Virginia Rheumatology Society
Wisconsin Rheumatology Association

CC: Senate Committee on Health, Education, Labor, and Pensions