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December 9th, 2019

Honorable Nancy Pelosi Speaker of the House 1236 Longworth House

Frank Pallone, Chairman Energy and Commerce Committee 2107 Rayburn House

Honorable Richard Neal, Chairman Ways and Means Committee 2309 Rayburn House Honorable Greg Walden, Ranking Member Energy and Commerce Committee 2185 Rayburn House

Honorable Kevin Brady, Ranking Member Ways and Means Committee 1011 Longworth House

Re: H.R 3, Drug Price Negotiation; Biosimilar Pricing

Dear Speak Pelosi, Chairman Pallone, Chairman Neal, Ranking Member Walden, and Ranking Member Brady,

The Global Healthy Living Foundation (GHLF) writes to you in regards to two provisions regarding biosimilar products that have been included in H.R. 3, the Lower Drug Costs Now Act; specifically, language pulled from the (1) to the Advancing Education on Biosimilars Act of 2019 and (2) the Bolstering Innovative Options to Save Immediately on Medicines (BIOSIM) Act. Biosimilars are biologic products that are highly similar, but not identical, to a licensed reference (or "originator") biologic product. Biosimilars have the potential to provide efficiencies and improve access to treatment for patients, and our organization fully supports greater education of the public of the values of these products.

By way of background, GHLF is a 20-year-old non-profit patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events, and online support and education. Our ArthritisPower registry of more than 22,000 patient participants was developed as part of the National Patient-Centered Clinical Research Network (PCORnet) with data capture mapped to the PCORnet Common Data Model. GHLF works to improve the quality of life for patients living with chronic disease by making sure their voices are heard and advocating for improved access to care at the local, state and federal level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease, and migraine. We are unabashed supporters of biosimilars and will release a patient-centered report on these medical products in the first quarter of 2020.

The Advancing Education on Biosimilars Act of 2019 would create federal programs to promote the use of biosimilars, including the development of continuing education programs for healthcare providers. In addition, the bill would require the FDA to create a website to educate patients and providers about biologics and biosimilars, and that provides information about interchangeability and processes for reporting adverse events that pose a risk to patient health and safety. We are very pleased to see this provision included in H.R.3 and believe it will increase awareness of both the availability and benefits of biosimilars, which we hope will also lead to increased use and reduced costs.

In addition to supporting initiatives such as the Advancing Education on Biosimilars Act that would educate the public on the importance of biosimilars, we also support efforts to lower drug costs for patients that





would have *real* results for patients. The BIOSIM Act would temporarily increase reimbursement rates to health care providers for a biosimilar from to a reference product's average sales price (ASP) from plus 6 percent to plus 8 percent. We recognize that the intent of this policy is to encourage the use of biosimilars that have lower ASPs or wholesale acquisition costs than corresponding biologics to reduce healthcare costs. However, while providing a "bonus" – in the form of a percentage above ASP benefits providers, it does not inure to the benefit of patients nor reduce their out of pocket expenditures.

Alternatively, we believe that the commitment to lower the maximum out-of-pocket spending cap to \$2,000 annually included in H.R.3 will have real benefits for Medicare beneficiaries and encourage Congress to continue to advance legislation that provides for this reduced cap. However, providing a financial incentive to doctors in the form of increased reimbursements distorts an already complicated and expensive healthcare system. Doctors and patients should be making medical decisions in the best interests of patients based on their clinical presentation and medical history, without a financial incentive to choose one therapy over another. The *only* incentive for providers should be getting the best medical treatment possible for their patients to lead to the best possible healthcare outcomes.

In addition, before we increase payment to providers, we should decrease or eliminate the direct costs to patients, including but not limited to copays, deductibles, supplemental or primary insurance premiums, and transportation. All of these patient costs have risen dramatically while incomes for the overwhelming majority of chronically ill patients have remained largely stagnant, forcing them to make health care decisions based on their ability to pay, not on their need. As we have in the past, we ask you to define the cost of health care in terms of what the patient pays, not the retail price of emergency room care, drugs, devices, doctor visits, or hospital inpatient stays. The patient is the only participant in the healthcare system who comes to the table with a checkbook. All other participants come to the table focused on profits. We encourage you to consider alternative incentives that drive the adoption of biosimilars that also reduce patients' financial burden, and for that reason, we oppose the inclusion of provisions in the BIOSIM Act in H.R.3.

Many patients in our community make use of biological products to effectively treat their chronic disease. Biosimilars have the potential to drastically reduce costs for our patients while maintaining similar health outcomes as their reference biologics. We stand ready to partner with you on efforts to achieve this goal.

Thank you for the opportunity to comment on the provisions within H.R.3. Please feel free to reach out to me at snewmark@ghlf.org for more information from the perspective of chronically ill patients, including those with psoriasis, inflammatory bowel disease and autoimmune arthritis.

Respectfully submitted,

Steven Newmark, JD, MPA

Director of Policy and General Counsel

Global Healthy Living Foundation



