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February 3, 2016

Representative Joe Pitts
Chairman
Energy & Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

Representative Gene Green
Ranking Member
Energy & Commerce Subcommittee on Health
2125 Rayburn House Office Building
Washington, DC 20515

RE: **Energy and Commerce Committee Subcommittee on Health Hearing February 4, 2016 entitled "Examining Implementation of the Biologics Price Competition and Innovation Act"**

Chairman Pitts and Ranking Member Green,

On behalf of the Global Healthy Living Foundation, I want to thank you both for your leadership and commitment to ensure the appropriate implementation of the Biologics Prices Competition and Innovation Act (BPCIA) and for the ongoing opportunity to provide input on behalf of patients with arthritis and other chronic diseases. We commend the Energy and Commerce Subcommittee on Health for its efforts in advancing the inclusion of biosimilars as a safe and cost-effective treatment option for millions of Americans suffering from chronic disease.

GHLF is a 501(c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. As a patient advocacy organization, GHLF represents more than 100,000 chronically ill patients and their caregivers. Many of these individuals have rheumatoid arthritis, take biologics, and have the potential to benefit greatly from biosimilars.

We speak to patients everyday about biosimilars and actively inform and educate our community about newly available treatment options and U.S. Food and Drug Administration (FDA) policy regarding biosimilars for the past five years. The resounding feedback we receive from patients on the topic is cautious optimism. Biosimilars represent hope to patients, both in the form of expanded treatment options and predicted cost savings.

In many cases, biologics have transformed patients' lives. Whether it's Mariah from Colorado who was able to finish her masters and law degree, Lisa from Washington who can take walks and spend quality time with her family again, Cindi from Texas who was able to take one last road trip with her elderly father, or Chantelle from Massachusetts who can finally wear her heels again, these drugs have meant miracles – small and large – to people near and far.

However, our community is also nervous because they know biosimilars could represent forced switches or substitution from insurers for treatments they've searched years to find and worked tirelessly to gain access to. In the case of Brenda from, North Dakota – it took a decade.

Yet our community remains optimistic that if implemented well, BPCIA will open doors to new, affordable treatments and enable them to live healthy, active lives. In order to stand a chance at achieving the promise originally intended by the BPCIA in 2010, we must address both patient and physician *confidence* in these products. We believe the FDA, the Centers for Medicare & Medicaid Services (CMS), and biosimilar manufacturers can take major steps toward doing this.

1. FDA needs to provide clarity on how it will work with biosimilar manufacturers to demonstrate that their facilities are capable of long term production without interruption. Absent this, informal defacto interchangeability could become the norm if biosimilar manufacturers cannot sustain production levels and patients must move from one biosimilar to another.

2. FDA can weigh a biosimilar manufacturer's safety and recall history against its ability to handle the much more fragile biosimilar molecules.

3. Biologic reference product manufacturers have a history of offering extensive support services such as patient/caregiver telephone hotlines, printed and electronic information, websites with contact-us capabilities, online chat, and, when applicable, copay cards and payer benefits navigation. CMS can help preserve these patient-centered services in ways that most appropriately align with its mission.

4. Extrapolation is important to ensure that biosimilars achieve the same credibility with healthcare professionals as the reference product, and that patients have the greatest access to treatment protocols. However, we are concerned about the application of extrapolation when the mechanism of action for the extrapolated indication is not clearly understood or the drug is considered scientifically or therapeutically outdated. Furthermore, if extrapolation is used to approve a given indication, it is essential that appropriate post-approval monitoring be in place. FDA can help in both areas by granting extrapolation based on best-in-class criteria, and by assigning PCORI Patient Powered Research Networks to perform post-approval monitoring using traditional research as well as patient-reported outcomes research. As a PCORI PPRN, GHLF, is ready to facilitate this work.

5. We acknowledge that FDA is not directly charged with cost issues in the drug approval process. However, CMS, within its legal parameters, is. Our goal is to help ensure that the predicted savings from biosimilars vs. biologics, benefit patients, not payers. This could occur through reduced premiums, copays and deductibles. GHLF is ready to work with CMS to help patients benefit in the savings biosmilars promise.

We think the House Energy & Commerce committee hearing on February 4th is a crucial opportunity to discuss these issues and to ensure that the patient voice is heard.

If the points above are not addressed, we fear the patient will ultimately be the loser in this frontier. While the science is key to approval of biosimilars for clinical use, the pragmatic application of biosimilars is where success will equally be measured.

I thank the House Committee on Energy & Commerce, FDA, and CMS for emphasizing the value of the patient perspective. We are ready to mobilize our patient community to create a better life for those who stand to benefit from biosimilars, and welcome input and collaboration.

Thank you for your time and attention.

Sincerely,

Seth Ginsberg
President, Global Healthy Living Foundation

CC:
Members, House Energy & Commerce Committee