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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
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Docket No. FDA-2019-N-6050 for *FDA/FTC Workshop on a Competitive Marketplace for Biosimilars*

Submission sent electronically via regulations.gov

To Whom It May Concern:

The Global Healthy Living Foundation (GHLF) is a 20-year-old 501(c)(3) non-profit patient-centered organization representing people with chronic diseases. We work to improve the quality of life for people living with these chronic diseases through research, education, support, and advocating for improved access to care. We thank both the Food and Drug Administration (FDA) and the Federal Trade Commission ("the Agencies") for your commitment to improving our healthcare delivery system and ensure that patients obtain needed benefits from a truly competitive biosimilar market.

The barrier for entry in the U.S. biosimilar market has been too high for too long. Europe released biosimilar guidelines in 2005; five long years later, legislative action in the form of the Biologics Price Competition and Innovation Act (BPCIA), part of the Affordable Care Act, finally spurred on movement here in the U.S. Still, it took another two years for the FDA to develop draft guidance – a full seven years after Europe.

Our country should provide needed health services to all our citizens, including the most vulnerable, chronically ill patients. The fiscal relief offered by a robust biosimilar market is long overdue. But, today the share of the biosimilar market in the U.S. greatly lags behind that of other developed countries. Not having a robust biosimilar market is a failure for our citizens.

One reason for this failure is simple education. Patients and providers are not properly educated on this topic. While the average patient understands the concept of a generic versus branded drug, even patients taking a regular biologic often cannot adequately understand what a biologic drug is with respect to a biosimilar. Even many trained medical professionals have difficulty understanding what a biosimilar is. This is indeed unfortunate as there are many benefits for patients to be had as a result of a growing biosimilar market.

Even our nation's elected leaders have lamented that U.S. health policy is "complicated." Indeed, it is. And explaining our complex system to patients is no easy task. To obtain the best care possible patients and their caregivers must navigate a complex web with insurers and providers to best understand what medications will be most affordable for caring for their condition. In the

world of biologics and biosimilars, concepts such as “rebate walls” and “buy-and-bill” have important consequences for patients trying to obtain their best course of treatment; too often, however, patients lack the education to adequately grasp these concepts in order to navigate our system.

It is not incumbent upon our government to put its proverbial thumb on a scale to influence outcomes that favors one group of manufacturers over another. For too long biosimilar manufacturers have sought out government as a means of encouraging the use of biosimilars through use of the proverbial thumb on the scale. We are not advocating for an unlevel playing field. To the contrary, our hope is that the Agencies will work to create a truly level playing field: one that does not show a bias for biosimilars or biologics. We believe that if a truly level playing field exists, a more robust biosimilar market will emerge, to the benefit of chronically ill patients.

Organizations such as GHLF work hard to make “better” patients – that is patients better prepared to deal with the medical and emotional impacts of their disease journey. We also work to educate patients on our complex healthcare ecosystem. But we cannot do it alone. Your Agencies can work in combination to better educate patients and providers about the benefits of biosimilars, which in turn will lead to a boost in the marketplace and a reduction in costs for all. Your Agencies also can work to eliminate some of the more byzantine aspects of obtaining affordable medications, such as “rebate walls,” or, at minimum, do your part to help educate patients about how such arrangements impact costs.

In public, many groups promote the idea that biosimilars are generic versions of biologics, notwithstanding the scientific difference between the two. However, there is a reason that manufacturers have not marketed biosimilars as akin to generics. Patients are accustomed to generics costing pennies compared to brand drugs. By allowing biosimilars to be marketed, sold, and reimbursed as something other than a generic it prevents people from making the connection that they are paying more than they normally would for a generic.

Patients cannot rely on the pharmaceutical or insurance industries for proper education on biosimilars. The patient is the only stakeholder that shows up to the medical game with a checkbook while everyone else – manufacturers, insurers, pharmacists, physicians – show up with a balance sheet. The patient sits there every year hoping that their costs don’t go up very much while every other stakeholder is trying to figure out how to have a positive balance sheet.

But increasing access to biosimilars goes beyond education. We have a complex healthcare delivery system that relies on volume, along with accompanying rebates, in order to create access. This means that manufacturers cannot go to an insurer and get placed on formularies without a high volume of products and associated high rebates. Education about biosimilars – or other therapies – means very little if products are “shut out” of the marketplace due to “rebate walls” and other associated tactics that pharmaceutical and insurance companies use.

Rebate walls create an anti-competitive marketplace for biosimilars and other medications. They are used by manufacturers to “bundle” rebates - that is, manufactures offer deep discounts to

insurers in the form of rebates, but only in exchange for adding a host of a manufacturer's medications to a formulary – to the detriment of other medications, such as biosimilars, trying to get on the same formulary. These "walls" that are erected do not allow for the growth of a robust biosimilar marketplace. That is not a free market – that is a market dominated by the few and powerful, to the ultimate detriment of patients unable to obtain access to cheaper medications.

We need a system that allows therapy options to compete based on their clinical outcomes and cost, not one that allows anti-competitive practices to stunt a potential pathway to lower drug costs.

But you know this. You have asked for comments on this topic because you recognize that the system is broken and that things need to change. So, how can the Agencies help patients?

You start by stepping up and creating an education program that is worthy of this innovative and cheaper class of medicine. This program must go directly to patients, caregivers, and providers and make clear that sometimes practices like step therapy and non-medical switching can lead to a benefit for the patient. Patients are often scared to switch off their effective brand medication because they have tried different biologics and oftentimes failed on them. There needs to be a better education involving both insurers and physicians to help explain that biosimilars can offer essentially the same drug but at a much cheaper cost.

Beyond dealing directly with biosimilar education, the Agencies can work to redefine what non-medical switching is and better regulate step therapy protocols. How does it make sense that a patient can fail on a biologic and then because of an insurance change to their formulary, they are forced to try and fail the biosimilar of the same drug that they already failed on? How does it make sense for a patient to fail on a biologic and then, due to step therapy, the next drug they are forced to try is the biosimilar version of that same drug? Your Agencies have the power to remove impediments such as these that cause needless delay in the care of chronically ill patients, along with increases in costs to the healthcare system.

With an increased effort to reach out and include the patient community in all parts of this process, patients will benefit from a more robust and competitive marketplace for biosimilars. We thank the FDA and the FTC for emphasizing the value of the patient perspective through public meetings, and we continue to mobilize our patient community to create a better life for those who will benefit from biosimilar therapies.

Respectfully submitted,

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Director of Policy and General Counsel