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August 14, 2020

Dr. Stephen Hahn, Director
Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Reauthorization of the Prescription Drug User Fee Act; Public Meeting; Request for Comment (FDA-2010-N-0128)

Dear Director Hahn,

The Global Healthy Living Foundation (GHLF) appreciates the opportunity to provide comments on the FDA's Prescription Drug User Fee Reauthorization Act (PDUFA) for fiscal years (FYs) 2023 through 2027. GHLF writes to offer considerations as work begins on PDUFA VII.

By way of background, GHLF is a 21-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 nearly 30,000 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 and federal level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease, sickle cell, lung disease, MS, diabetes, migraine, and others.

Over time, user fees have played an increasingly significant role in the FDA's budget and have become essential to accomplishing the FDA's mission and ensuring patients have access to safe and effective treatment options. GHLF has three main recommendations for PDUFA VII that we believe will continue to improve patient care.

Integrate the Patient Perspective in Drug Development and Regulatory Decision-Making

We commend the FDA for recognizing that patients are uniquely positioned to provide insights on their disease experience and the adequacy of existing treatment options. We appreciate the FDA capturing the patient voice in drug development in PDUFA VI and we support plans for PDUFA VII to continue to obtain valuable patient perspectives through public meetings and the *Voice of the Patient* Report. At GHLF we connect one-on-one with patients and use their insights to create robust patient-centered resources. From our work, we know that patients are experts on what it is like to live with their disease and can provide an important perspective on the impact of their disease and help uncover what patients want from treatment. Patient advocacy organizations like GHLF can help contribute by lending patient perspectives to ensure the success of drug developments. Under PDUFA VII, we look forward to the continuation of the Patient-Focused Drug Development (PFDD) program and we hope that FDA will look to us and similar organizations to further include the patient experience into the decision-making process.

Create Mechanisms to Prevent Drug Shortages

Following learnings from the COVID-19 pandemic, now more than ever we can appreciate the importance of continued access to medications. During the pandemic, patients across the country experienced drug shortages. From GHLF's patient community, many with lupus and rheumatoid arthritis were negatively impacted by the hydroxychloroquine shortage. Many of our patients had delays in accessing their usual treatment, while others were unable to fill their prescription at all. Drug shortages restrict access to essential medications which is detrimental for the health of our communities and especially for chronically ill patients who rely on medications to maintain remission. Reducing the barrier to access medication ensures patients will receive their medications sooner and be able to treat their disease and remain in a stable condition, therefore lessening the risk of a flare-up. We believe that with the help of the highly qualified experts at your disposal, the FDA should increase monitoring efforts and timely reporting of drug shortages. We want to stress the importance of having mechanisms in place to prevent drug shortages before they become a potential issue.

Use Real-World Evidence for Telehealth Expansion

We believe one of the vital next steps in the PDUFA process is to use real-world evidence (RWE) to expand telehealth. During this pandemic we witnessed patients and providers embrace telehealth and digital health technologies. Telehealth helps patients to stay connected with their doctor and empowers patients to manage their chronic conditions outside of traditional care settings. And for the first time, there is truly quantifiable data from every patient community around the country.

Our patient community is in favor of expanded telehealth. GHLF asked our patient community to rate their experience with telemedicine over the past two months on a scale of 1-10 (10 being an excellent experience). Seventy-three percent of respondents said they have used telemedicine in the past two months and of those who have used it, they rated with experience as a 7.9, with 41 percent giving it a score of 10.

Telehealth allows providers to monitor patients from afar and it allows patients to connect with their doctor on their medications, condition, and discuss changes in their treatment plan. With so many patients suffering from chronic pain and chronic disease, we need innovative solutions. We recognize and thank the FDA for continually using real-world information to innovate and evaluate research and product. We believe the FDA can be a leader in ensuring all Americans have access to safe and effective telehealth services that are of high-quality by using RWE to provide recommendations in regulatory decision-making. It is critically important as we enter this new normal, that we have an effective telehealth system so patients can continue their regular treatment plans with their doctor.

We do appreciate the opportunity to provide comments on regulatory changes that will have direct impacts on our patient community. Please contact 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 or any other chronic conditions.

Respectfully submitted,



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Director of Policy and General Counsel
Global Healthy Living Foundation

