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December 20, 2019

Stephen Hahn M.D.  
Commissioner  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Re: Docket No. FDA-2019-D-4247-0001, draft guidance titled, “Patient-Focused Drug Development: Methods to Identify What Is Important to Patients”**

Submitted electronically via regulations.gov

Dear Commissioner Hahn,

On behalf of the Global Healthy Living Foundation (GHLF), congratulations on your recent confirmation as Commissioner of the Food and Drug Administration (FDA). We look forward to continuing our productive partnership with the FDA under your leadership and thank you today for the opportunity to comment on the draft guidance “Patient-Focused Drug Development: Methods to Identify What Is Important to Patients” (Docket No. FDA-2019-D-4247-0001). GHLF is a 20-year-old 501(c)(3) patient organization reaching millions of chronically ill patients and their caregivers across the country through social media, community events and our online support and education. 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 community level. Our patients suffer from chronic conditions including arthritis, psoriasis, gastrointestinal disease, cardiovascular disease and migraine.

GHLF commends the FDA for its ongoing efforts to implement the provisions in the 21<sup>st</sup> Century Cures Act that pertain to patient-focused drug development and greatly appreciates the opportunity to comment on this second of four anticipated draft guidance documents that will aim to incorporate the patient voice into regulatory science and regulatory review. We have previously shared information with the FDA via other dockets and directly in meetings with the Center for Devices and Radiological Health (CDRH) about our Patient-Powered Research Network, a 24,000-member patient registry called ArthritisPower, initially funded by the Patient Centered Outcomes Research Institute (PCORI). Using data collected via smartphone app and equivalent web-based platform, ArthritisPower enables patients with rheumatoid arthritis (RA), spondyloarthritis (SpA), and other rheumatic and musculoskeletal diseases, inflammatory bowel disease, and skin conditions such as psoriasis, to actively engage in health research while monitoring their own progress and managing their disease in collaboration with their clinical care team. Thus our innovative patient-participation model allows ArthritisPower to achieve its primary mission: to conduct and translate research via collaboration among patients, providers, comparative effectiveness researchers, and informatics experts.

ArthritisPower data also support regulatory applications. Understanding how patients may respond to treatments over time, patient-reported outcomes can also help determine what endpoints are important to measure when evaluating the efficacy of treatment or medical devices, and the impact of these endpoints on regulatory protocols. Our registry has the capacity to collect and integrate patient-generated data with linkage to other data sources (i.e., electronic health records and claims data), and to enhance patient leadership in the design and implementation of research and dissemination of findings. Disease-specific registries of real-world patient-generated data collected by non-profit organizations like ArthritisPower can serve as valuable non-governmental infrastructure to assist Federal efforts to incorporate the patient perspective into the discovery, development, and monitoring of medical products. As you consider how best to identify and understand what is important to patients, we offer ArthritisPower as another tool researchers and regulators may use to protect the safety and advance the health of the U.S. public.

We are also pleased that the draft guidance included a section on considerations for the use of social media platforms. GHLF has a long history of leveraging social media with its patient community to support the organization's education, support, advocacy, and research mission, such as rapid sharing of safety alerts and drug recalls, or driving patient engagement in ArthritisPower research. Our active platforms include Facebook with more than 118,000 likes and thousands of interactions per day, Twitter chats called CreakyChats which average 5.5 million impressions, and a growing active Instagram base of more than 4,700. Using our social media leadership position, GHLF is ready to assist researchers and the FDA with efforts to recruit participants for clinical research and to share data analytics that may inform the design of study protocols.

Thank you for considering our comments and for your efforts on this important draft guidance. Please contact me at [snewmark@ghlf.org](mailto:snewmark@ghlf.org) if we may be of further assistance with your work on patient-focused drug development or if you have questions on our comments.

Sincerely,



Steven Newmark  
Director of Policy and General Counsel  
Global Healthy Living Foundation

