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March 19, 2019

Division of Dockets Management (HFA-305)
US Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2018-N-4731 for “Patient Engagement on Clinical Trials; Public Workshop; Request for Comments.”

Submitted electronically at www.regulations.gov

To Whom It May Concern:

The Global Healthy Living Foundation (GHLF) appreciates the opportunity to provide comments on the draft guidance entitled “Patient Engagement on Clinical Trials; Public Workshop; Request for Comments” published in the Federal Register on February 11th, 2019.

GHLF is a 501(c)(3) patient organization that works to improve the quality of life for people living with chronic disease by making sure their voices are heard. GHLF represents more than 100,000 chronically ill patients and their caregivers across the country. GHLF is pleased that the Food and Drug Administration (FDA) recognizes that there is a need to address the barriers that patients face when attempting to participate in clinical trials, and that FDA is giving particular focus to the patient perspective of these barriers. Through its patient-centered drug development efforts, FDA has already worked to incorporate the patient perspective in the review of medical products, and we believe that incorporating this perspective into addressing barriers of participating in clinical trials will further enhance the ability of both FDA and manufacturers to incorporate patient feedback.

As an organization that has designed and conducted patient-centered outcomes research for more than five years, GHLF has experienced firsthand the value of incorporating patient perspectives and patient-centered outcome measures into studies. GHLF created ArthritisPower in collaboration with our CreakyJoints arthritis patient community and rheumatologists at the University of Alabama at Birmingham (UAB) to assist in evidence generation to support decision making for people living with arthritis and other musculoskeletal conditions. Supported by a multiyear, multimillion-dollar investment by the Patient-Centered Outcomes Research Institute (PCORI), ArthritisPower is the first ever patient-led, patient-centered research registry for joint, bone, and inflammatory skin conditions. ArthritisPower is led by a 10-member Patient Governor Group that provides input from research question inception to public dissemination of findings.

GHLF believes in the critical importance of providing information and valuable insights back to study participants at the same time that we ask for their data for research. The associated ArthritisPower mobile app allows patients to track and share their symptoms and treatments while simultaneously participating in research via informed consent. The registry has consented nearly 18,000 patients, more than half of whom have some form of inflammatory arthritis or other autoimmune condition. Through guidance from others, and simple trial and error, GHLF has learned that heeding the experience and insights of patient participants strengthens our research. GHLF is eager to share what we have learned and to continue advancing the meaningful and productive incorporation of patient perspectives in clinical trials and other research.

Incorporating the patient perspective in clinical trials can provide powerful insights into what can be done to dispel and mitigate apprehension on the part patient to participate in trials simply as “subjects”. It can enhance the patient’s trust and compliance in clinical trial participation. Further, it can help integrate valuable insights into how patients perceive risk, where patients can access information on the specific trials that may be suitable to their individual needs, how to ensure that the goals that remain important for patients are kept in the forefront and hence in the development of meaningful endpoints. It can help the research community to develop and provide transparent information so patients are able to evaluate the risks, understand what it means to provide consent and learn what it means to comply with the awareness that they may voluntarily withdraw at any point during their participation. Further, patients may be able to provide strong insights into how trials can be more inclusive and representative by including diverse populations. All this will help make trial designs and processes more patient-friendly and may thus increase participation and retention during the trial itself.

Thank you for your work on this and we look forward to assisting you in incorporating patient perspectives of clinical trials and the barriers to participation into FDA’s regulatory approach. We are ready to help any way we can. For questions regarding GHLF or the above comments, please contact me at svenky@ghlf.org.

Sincerely,



Shilpa Venkatachalam, PhD, MPH
Associate Director, Patient-Centered Research
Global Healthy Living Foundation

