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August 15th, 2019

Norman Sharpless, MD
Acting Commissioner
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2019-D-1536 for “Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework.”

Submitted electronically via regulations.gov

Dear Acting Commissioner Sharpless,

On behalf of the Global Healthy Living Foundation (GHLF), thank you for the opportunity to comment on the draft guidance “Opioid Analgesic Drugs: Considerations for Benefit-Risk Assessment Framework” (Docket No. FDA-2019-D-1536). 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. Many of those in our community deal with debilitating pain and opioid medications are a necessary part of their treatment regimes. Considering that this class of drugs has such a significant impact on patients with legitimate pain and our society, we greatly appreciate the Food and Drug Administration’s (FDA’s) efforts to provide clarity on their assessment of both the benefits and risks of opioid medications.

GHLF would like to offer our support of the finalization of this draft guidance document intended to help industry understand the FDA’s thinking on benefit-risk assessments for opioid analgesic drugs. Chronic pain is a real public health problem that is nothing short of debilitating for those going through it. Individuals suffering in pain simply cannot go to work, have difficulty being present for their families, and often have difficulty simply interacting with society. We support the finalization of this guidance so that patients within our community suffering with legitimate pain can have access to both safe and effective medications to help them live fuller, more productive lives.

The opioid crisis is real. We are at a point where few Americans do not know of someone who has suffered as a result of addiction. In representing patients who suffer daily in physical pain, we promote alternative pain management techniques vigorously: where viable, we encourage our patients to try physical therapy, acupuncture, and yoga/stretching. Additionally, we support the research and development of non-opioid pain medications because we believe that opioids should never be used in this first instance for chronic pain. If patients find themselves needing an opioid medication, then it should be used only under the strictest guidance from physicians. Because of the significant consequences of opioid use, we greatly appreciate that the FDA has incorporated clear expectations for industry associated with

answering numerous benefit-risk questions with a focus on both individual patients and to society as a whole.

While we support the finalization of the document, GHLF would also like to offer several specific comments on the patient's perspective of benefit and risk:

- The FDA has made tremendous improvements to better incorporate the perspective of patients into their activities and we would like to encourage the FDA to continue to have this focus by emphasizing the importance of the patient voice in the final document. As relayed above, patients with legitimate pain have a valuable perspective to share. GHLF seeks to minimize the stigma associated with their desire to appropriately manage their pain. Allowing them to have a voice in this conversation will help ensure that the public emphasizes the need for pain alleviating medications and for medications and strategies that will minimize patient-specific and public impacts of these drugs.
- We would like to thank the FDA for including questions pertaining to adverse events associated with taking opioid medications as prescribed. Patients with pain are seeking an improved life condition and we hear from patients that the side effects associated with opioids are often quite problematic. We urge the FDA to keep safety questions relating to side effects including respiratory depression, sedation, and constipation in the finalized document.
- As the FDA understands, pain is a subjective experience that can be difficult to measure. Therefore, we encourage the FDA to accept all types of data to better understand the safety and effectiveness of opioid medications including patient-reported outcomes and other real world data. Giving a voice to patients has been a primary driving force behind GHLF's activities since its founding. As such, we are proud to be able to offer patients the option to participate in ArthritisPower, an application used to collect patient reported outcomes. Disease-specific registries and patient-reported data collected by non-profit organizations like ours have served as valuable tools in other government efforts associated with the incorporation of the patient perspective into the discovery, development, and delivery lifecycle of a medical product. As an example, the National Patient-Centered Clinical Research Network (PCORnet) is aimed at incorporating the experiences and concerns of patients through standardized measures and instruments and we are honored to contribute to this important initiative through our own Patient-Powered Research Network (PPRN), ArthritisPower. We urge the FDA to update the document to note the importance of patient-reported outcomes, other types of real world data, and patient registries in general.

Thank you for considering our comments and for your efforts on this important draft guidance. Please contact me at snewmark@ghlf.org if we may be of further assistance with this proposed rule or if you have questions on our comments.

Sincerely,



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

