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Scott Gottlieb, MD
Commissioner
Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852


On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to cancer patients, survivors, and their loved ones, we appreciate the opportunity to respond to the request for comments regarding the Benefit-Risk Assessments in Drug Regulatory Decision-Making. As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology professionals in the United States, CSC has a unique understanding of the cancer patient experience. Each year, CSC serves more than one million people affected by cancer through its network of 44 licensed affiliates, more than 120 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $40 million in free, personalized services each year to individuals and families affected by cancer nationwide and internationally.

Additionally, CSC is home to the Research and Training Institute—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones, as well as the Cancer Policy Institute which focuses on advocacy activities to ensure that patients have access to timely, affordable, high-quality, comprehensive care. This combination of direct services, research, and policy uniquely positions CSC to provide feedback on this topic to the FDA.

CSC recognizes and values the full patient experience throughout the entire continuum of care, and works to bring patient perspectives to policy decision makers such as the FDA as you make decisions about the future of medical treatments. CSC supports the development of therapies that can improve the lives of people impacted by cancer and believes that patients deserve access to affordable, high-quality medications that best address their unique needs, values, and preferences. As such, we offer the following considerations in the development of the FDA’s Benefit-Risk Assessment in Drug Regulatory Decision-Making.

**Development of Benefit-Risk Criteria**
Incorporating the patient voice into Benefit-Risk Assessments is essential to understanding the way a drug or biologic impacts the whole patient, and allows doctors to identify patient needs and challenges early on, allowing them to intervene as appropriate. This provides the best opportunity for the patient to adhere to the recommended treatment protocol and contribute meaningful data to the process. Outcomes classified as “benefits” or “risks” vary between each individual patient. What one patient finds tolerable or worth enduring for the anticipated benefits may not be the same as another patient. Participants in clinical trials are also not representative of the full diversity of patients who will be prescribed the drug in
a real world setting. CSC recommends that the FDA find ways to incorporate benefits and risks as defined by the individual patient into the trial phase. The collection of data of patient perceived benefits and risks depending on personal characteristics, type and progression of disease, lifestyle factors, and various comorbidities, would allow the FDA to be better equipped to evaluate whether benefits outweigh the risks of a certain treatment in diverse populations. Further, the FDA would be better able to communicate the potential for these patient-defined benefits and risks to new patients both when they are making treatment decisions as well as throughout their treatment experience. Patients, families, and caregivers should be able to take ownership of their health and have the flexibility and information to make choices as they seek care. However, they must be equipped with the tools to ensure that they can make informed decisions that are right for them.

Post-Approval Review
The incorporation of the patient experience should also continue past the approval of the medication and into the post-approval review setting. The FDA should require that manufacturers continue to survey patients taking the drugs in a real world setting to assess: (1) the patients’ ongoing reaction to the benefits and risks of the medication based on their personal needs, values, and preferences; and (2) patients’ level of social and emotional distress as a result of the full treatment experience, taking into account the impact that any of the potential benefits and risks may have in their lives.

PDUFA V also commits the FDA to require risk evaluation and mitigation strategies (REMS) to manage a known or potential serious risk associated with a prescription drug or biologic products in the post approval phase. REMS should be applied not only to physical risks but psychosocial risks as well. The FDA should continue to collect patient experience and distress data in the post approval phase to allow for ongoing monitoring of the risks associated with the drug in the wider population. This ensures that the FDA can re-evaluate the weight of associated risks and benefits as new information, and the effect of a drug on diverse populations, becomes available. This information can then be publicly communicated to patients, caregivers, researchers, scientists, policymakers, and other stakeholders. In an era of precision medicine, this type of holistic patient-directed information will be invaluable.

Conclusion
We appreciate the opportunity to provide comments on the ongoing development of Benefit-Risk Assessments in Drug Regulatory Decision Making at the FDA. CSC believes that the patient voice should be meaningfully incorporated into every step of regulatory decision-making, and we hope that the FDA will work to further incorporate patient needs, values, and preferences into its Benefit-Risk assessments. CSC stands ready to serve as a resource to the FDA as we work together to protect patients and elevate their voices in order to inform regulatory decisions. Please reach out to me at linda@cancersupportcommunity.org for more information.

Sincerely,

Linda House, RN, BSN, MSM
President
Cancer Support Community Headquarters