June 12, 2017

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted electronically


Dear Sir or Madam:

On behalf of the Cancer Support Community (CSC) and the patients we represent, we thank you for the opportunity to provide comments on the United States Food and Drug Administration’s (FDA or Agency) “Enhancing Patient Engagement Efforts Across FDA; Establishment of a Public Docket; Request for Comments.” First and foremost, we commend the FDA for their continued recognition of the importance of the patient voice.

As the largest direct provider of social and emotional support services for people impacted by cancer, and the largest nonprofit employer of psychosocial oncology mental health 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 170 locations, telephone helpline, and a vibrant online community. We deliver more than $40 million in free, personalized services each year to individuals and families impacted by cancer.

Additionally, CSC is home to the Research and Training Institute— the only entity of its kind— focusing solely on the cancer patient experience. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry®, publications and peer-reviewed studies on distress screening, the psychosocial impact of cancer, and cancer survivorship, to name a few.1 This combination of direct services and cutting edge research uniquely positions

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1 To see more information, please visit: http://www.cancersupportcommunity.org/publications-presentations
CSC to provide policymakers and regulators with feedback based on evidence as well as our views on the real world impact.

CSC is encouraged by the FDA’s continued commitment to better understand and integrate the perspectives of patients in the drug development process through PDUFA V and as proposed in the PDUFA VI commitment letter. We are heartened by the Agency’s growing acceptance and inclusion of real-world evidence and patient reported outcomes. The CSC believes that the formation of a dedicated Office of Patient Affairs (the Office) to create and maintain meaningful relationships with patients, and the resources and knowledge of their respective advocacy organizations, will ultimately change the way that clinical trials are designed, and drugs and devices are developed to not only be more patient-centric, but ultimately to be patient-directed. As the FDA considers the structure and function of the Office of Patient Affairs, the CSC recommends the following:

**Build on Current Progress**
The existing Office of Health and Constituent Affairs has provided opportunities for patient perspectives to be incorporated into the work of the FDA and the CSC would like the Office of Patient Affairs to build upon the relationships and progress made by the Office of Health and Constituent Affairs, which has shown openness, flexibility, and goodwill towards patients and advocacy organizations. The CSC does not want to see bureaucratic hurdles or restricted access put in place, especially for the patient advocacy community that may already have well-established relationships within the agency. The CSC would not be supportive of additional gatekeepers creating distance between the advocacy community and FDA leadership. In addition, it is still unclear how this Office will work with the Oncology Center of Excellence and other centers which hold much promise for the oncology advocacy community.

**Develop a Patient Priority Agenda and Communications Strategy**
Through the Office of Health and Constituent Affairs, the FDA has been receiving input and feedback from patients on what is important to them and where they would like to see changes and improvement in FDA processes. If the Office of Patient Affairs is launched, it will be incumbent upon the Agency to outline priorities that have been informed by the patient and advocacy communities. For example, issues of common concern for patients such as “right-to-try” or compassionate use inquiries should be high on the list of priorities on which the Office must provide transparent, easy-to-understand, and up-to-date information. Further, processes for participation should be readily available to patients and if patients will not qualify for reasons such as conflicts of interest, the policies governing those decisions should be explicit and provided in easy-to-understand language. Patients should also be able to seek recourse if they believe their voices are integral to conversations and such conflicts cannot be avoided. These are only a few examples of items that should inform an agenda which should be readily available to stakeholders.
Further, a clear communications strategy should be put in place to help patients understand their options to engage the FDA including opportunities to serve as representatives on panels and offer comments on proposed rules and regulations. These communications should proactively be delivered to patients electronically, and with ample time to respond. Additionally, patients should be able to quickly locate contact information for appropriate staffers should they have feedback, questions, and concerns. Patients must be able to understand the goals of the Office so that they can provide input to influence an agenda that should continue to evolve with the ever-changing health care and cancer care landscape.

**Collect Data that are Meaningful to Patients**

The CSC is supportive of the Agency’s efforts to include real-world data and patient-reported outcomes into the drug review and approval process. As the Office works to improve the Agency’s “nuanced understanding of the patient experience of disease,” the CSC offers our Research and Training Institute and can ask our network of patients to help inform this process.

The CSC looks forward to the opportunities that the proposed Office will provide to advance the current standard of patient feedback, which currently consists of mostly physical measures recorded as a part of the clinical trial. Frequently, data that are collected in clinical research are data that are medical in nature and readily measurable rather than those outcomes that are most meaningful to patients. Real-time feedback should be collected throughout the clinical trial process and should include more than just the physical burdens of disease (i.e. disease symptoms, treatment side effects, and functional status). The current clinical trial process and the patient-reported outcome (PRO) structure should seamlessly incorporate psychosocial measures (i.e. distress) in the same way physical measures (i.e. blood pressure, hemoglobin, etc.) are measured, addressed and recorded. It is our view that such measures are relevant to FDA’s determination of the safety and efficacy of a drug product.

The CSC encourages the FDA to consider using the data collected through validated tools to gather real-time feedback from patients on measures that truly represent the patient experience and impact on quality of life. As the FDA begins to plan stakeholder meetings on real-world evidence, we ask the Agency to include psychosocial and behavioral health experts to ensure that data sources under consideration are actually capturing values that matter to patients and accurately reflect the true and comprehensive impact of an investigational drug product on an individual. The FDA should work with patient advocacy organizations, as well as individual patients, to...
incorporate patient-directed experience measures into clinical trial design that capture outcomes that are meaningful to patients.

Outline the Authority of the Office of Patient Affairs
In order for the Office of Patient Affairs to meaningfully engage and support patients, and enhance the science of eliciting and integrating the patient experience, it is essential for the Office of Patient Affairs to have explicit authority to influence clinical trial protocol. In the absence of this explicit authority, the Office of Patient Affairs will simply be an office that can share information about the FDA with patients and advocates while acting as a repository for critical data with no mechanism to create meaningful change.

In addition, to fully understand the comprehensive needs of patients and to effectively communicate this information, the incoming Director of the Office of Patient Affairs and/or senior leadership of the Office should have a high degree of psychosocial expertise, particularly among staff who will communicate patient community perspectives around trial design and the review of products to the appropriate divisions. Without this expertise on staff many of the complex, comprehensive issues that are important to patients may not be treated with the appropriate priority.

In closing, the CSC would like to thank the FDA for the opportunity to submit these comments. The CSC is supportive of the development of the Office of Patient Affairs and is committed to collaborating with the Agency to ensure that the measurement of the patient experience is truly meaningful to patients. If we can serve as a resource to the FDA, particularly as you consider the future of this Office, please do not hesitate to contact me at Linda@cancersupportcommunity.org or 202-650-5382.

Sincerely,

Linda House
President
Cancer Support Community Headquarters