August 14, 2015

Stephen Ostroff, M.D.
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Re: Request for Comments on July 15, 2015 Prescription Drug User Fee Act (PDUFA) Public Meeting

Dear Dr. Ostroff:

On behalf of the Cancer Support Community, an international nonprofit organization that provides support, education and hope to over 1 million people affected by cancer each year, we appreciate the opportunity to respond to the request for comments regarding the July 15th, 2015 public meeting on the Prescription Drug User Fee Act (PDUFA).

We welcome the opportunity to be involved in this process, and look forward to submitting our intent to participate in the PDUFA stakeholder meetings. While CSC certainly supports the steps the Food and Drug Administration (FDA) has taken to ensure the patient voice is elevated in the drug and device approval process, CSC would like to encourage your thinking about novel opportunities to gather information in real-time and incorporate it as a part of the data submission package.

As the reauthorization process moves forward, we want to work with you to ensure that the FDA is promoting best practices with respect to psychosocial oncology care across its operating divisions. The benefit of psychosocial support as a part of comprehensive cancer care has been well known and documented. Most notably, the Institute of Medicine 2008 report *Cancer Care for the Whole Patient* specifically states, “Today, it is not possible to deliver good-quality cancer care without using existing approaches, tools, and resources to address patients’ psychosocial health needs.” The FDA approval process is a very effective way to meet this mandate through the incorporation of patient quality of life tools and patient reported outcomes measures. Specifically, by integrating routine screening for psychosocial distress into the clinical trial process and required elements for data collection, researchers, patients and FDA reviewers will be able to understand key elements of the patient experience directly related to the clinical approval decision at hand. Moreover, collection and reporting of this data over time will provide the community at large information that could be used to benefit future clinical trial design.

With regard to the current engagement of patients, CSC recognizes and appreciates the work of the FDA to include patients and patient advocates on advisory panels and as a part of regular
FDA hearings and Patient Focused Drug Development. However, CSC fully believes that there is an opportunity for patients to provide substantive feedback earlier in the development process. Specifically, the FDA should include patients in the early discussions with sponsors as trials are being formed. Patients are often able to provide feedback that will inform both clinical and experiential utility as well as efficient trial design. We look forward to working with you to improve these areas.

Finally with respect to the public hearing process, CSC recognizes that there is value to hearing feedback obtained in this way. CSC is concerned that the feedback may not be a comprehensive perspective given the inability of many to attend due to physical, geographic or other limitations. CSC is also concerned that local/regional bias related to access and care may contribute to limited information. As the reauthorization process moves forward, CSC encourages the FDA to make a larger commitment to securing feedback by working with patient groups, community organizations and other mechanisms that allow the collection of a more comprehensive view of the patient experience.

Thank you for your consideration of these important matters.

Sincerely,

Linda House
President

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