February 16, 2018

Scott Gottlieb, MD
Commissioner for Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Re: Docket No. FDA-2017-N-5896: Patient-Focused Drug Development: Guidance 1- Collecting Comprehensive and Representative Input; Public Workshop; Request for Comments

Dr. Gottlieb,

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 attend the workshop for and provide comments on Guidance 1 of the Patient-Focused Drug Development series.

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 over 40 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. The Research and Training Institute has contributed to the evidence base regarding the cancer patient experience through its Cancer Experience Registry, various publications and peer-reviewed studies on distress screening, and the psychosocial impact of cancer and cancer survivorship. This combination of direct services and research uniquely positions CSC to provide valuable patient and evidence-informed feedback to the U.S. Food and Drug Administration.

CSC applauds the FDA’s efforts to improve the patient centered drug development process with an appreciation for the full range of patient experiences. We are grateful for efforts to involve the greater patient community and respectfully submit the following comments.

It is incumbent upon the FDA, industry, academic institutions, members of the health care team, patient advocacy organizations, and other stakeholders to consistently and meaningfully seek robust patient feedback and patient experience data at all points along the research and care
continuum. As noted in guidance document 1, patient input cannot only inform the clinical context and provide insights to frame the assessment of benefits and risk but also serve as a direct source of evidence for use in clinical studies in investigational therapies. Clinical trial design, trial endpoint selection, and regulatory reviews should all include meaningful patient feedback and patient experience data. Ultimately, this information can be incorporated into drug labeling to better inform decisions by patients, their loved ones, and their health care team.

**Inclusion of Psychosocial Impacts**

We are pleased to see the inclusion of the definition of patient experience data as amended by the Food and Drug Administration Reauthorization Act of 2017, which includes both physical and psychosocial impacts of a disease or condition, or a related therapy of clinical investigation. As has been documented across a number of esteemed organizations including the Institute of Medicine, “[t]oday, it is not possible to deliver good-quality cancer care without using existing approaches, tools, and resources to address patients’ psychosocial health needs.” Additionally, as the comprehensive care conversation evolves and becomes more inclusive of the patient, it is no longer acceptable to limit patient assessments to disease symptoms, treatment side effects and physical functioning. Additional data collected through distress screening (e.g., concerns related to disruption of work/family life [due to the regimen], concerns related to nutrition, financial impact and others) would provide meaningful feedback through the patient voice in real time about issues that may not be identified through the current measures.

The Institute of Medicine concluded in 2008 that comprehensive cancer care must include psychosocial care. In 2016, the American College of Surgeons Commission on Cancer (CoC) began requiring CoC-accredited institutions to screen all cancer patients for distress and refers to this practice as a critical first step to providing high-quality cancer care. Patients entering clinical trials at CoC sites are guaranteed distress screening services, yet they are not promised this same standard of care in all clinical trials. Just as a person’s blood is measured in a clinical trial so should their level of distress. Patients entering clinical trials at cites certified by the Commission on Cancer are guaranteed this level of care. Psychosocial distress screening along with follow-up care is associated with an improvement in patient outcomes (quality of life and survival rates).

**Patient Experience in Clinical Trials**

Clinical trials that incorporate patient experience data and distress screening allow us to better understand and address patient needs and concerns. The intent of screening for and documenting patient distress/experience as a part of the clinical trial is to better understand patient response to each arm of the trial, similar to documenting physical response to the interventions in each arm of the trial. In this scenario, the trial control arm would, in fact, be the control arm for the sponsors’ studies. The same screening would be applied to each arm which would allow investigators to understand if one intervention led to more or less distress than another. For example, a weekly dosing schedule might create more of a disruption to work/family/home life than an every three or four week schedule. Patients who are distressed about such a disruption have an increased risk for clinical depression.

Patients who are highly distressed about disruption to work, family, or school life have a 92% probability of developing a clinical diagnosis of depression. For patients in a clinical trial where
the study arms have dosing options on a weekly or once per three week schedule, patients should be screened for how the interventions impact their work, family, and school life. By definition, the patients (and caregivers) in the weekly dosing arm will have to take time off from work three times more often than the patients in the other arm. The patients in the weekly dosing arm will have to pay three times the travel expenses to get to treatment and they will encounter weekly toxicities associated with the administration of the product, among other stressors. Distress caused by or exacerbated by trial design can contribute to trial compliance and ultimately, abandonment of participation which is of great concern to the sponsor. The ability to identify and manage any distress caused by this disruption is an important opportunity for sponsors. Therefore, information about levels of experiential distress should be collected, reported on, and used as a part of a shared decision-making process both for the benefit of the patient and their family but also for future trial design and intervention.

Post Approval Review
As noted in our November 2017 comment letter to the FDA regarding benefit risk assessments, we believe that the incorporation of the patient experience should 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 medications in real world settings to assess: 1) the patients’ ongoing reaction to the medications 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 risks and benefits may have in their lives.

The Cancer Support Community continues to support the FDA’s efforts to promote the collection of patient experience data and we believe that the patient voice should be meaningfully incorporated into every step of regulatory decision making and throughout the drug development process. We would like to commend the FDA for working to bring together representative input to ensure that patient experience data is an integral part of the future of drug development, and we thank the FDA for the opportunity to submit these comments. CSC stands ready to serve as a resource to the FDA as we collectively work to protect patients and elevate their voices throughout our regulatory processes. If we can serve as a resource, please contact me at efranklin@cancersupportcommunity.org or 202.650.5369.

Sincerely,

Elizabeth Franklin, LGSW, ACSW
Executive Director, Cancer Policy Institute
Cancer Support Community

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1 Andersen, B.L., Thornton, L.M., Shapiro, C.L., Farrar, W.B., Mundy, B.L., Yang, H.C., and Carson, W.E. (2010). Biobehavioral, immune, and health benefits following recurrence for psychological intervention participants. Clinical Cancer Research; 16(12); 4490.