March 21, 2019

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Re: Docket No. FDA-2018-D-4455: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data; Request for Comments

Dear Dr. Gottlieb,

On behalf of the Cancer Support Community (CSC), an international nonprofit organization that provides support, education, and hope to people impacted by cancer, we appreciate the opportunity to submit the following comments in response to: Developing and Submitting Proposed Draft Guidance Relating to Patient Experience Data: Guidance for Industry and Other Stakeholders (Draft Guidance). CSC applauds the U.S. Food and Drug Administration (FDA or Agency) for its efforts to provide information to stakeholders on how to submit a proposed draft guidance relating to patient experience data for consideration by FDA as well as other opportunities for stakeholders to share patient experience data with the FDA to advance drug development outside of the guidance process. FDA’s commitment to providing stakeholders with understandable, accessible, and effective guidance that ensures patient experience data is included as an integral part of drug development will prove invaluable to patients, their families, and caregivers.

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 45 licensed affiliates, more than 170 satellite locations, and a dynamic online community of individuals receiving social support services. Overall, we deliver more than $50 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 (RTI)—the only entity of its kind focused solely on the experiences of cancer patients and their loved ones. The RTI 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 FDA.

FDA guidance documents are non-binding on both the FDA and the public - with the use of the word should in guidance documents meaning something is suggested or recommended, but not required. CSC noted in a previous comment to this Agency that if FDA’s policy is that patient perspectives and patient preferences are crucial to determining the safety and efficacy of a product then the Agency should require that innovators capture this information throughout the drug discovery and development process.1 Similarly, FDA acknowledges the importance of patient experience data in this Draft Guidance by specifically recognizing the valuable and informative role patient experience data may play in addressing specific topics and questions throughout the medical product lifecycle and as the medical product development moves into premarket review and then the post market setting, respectively. Agreeing with FDA’s assessment that patient experience data may offer valuable and informative information, and to ensure such valuable and informative information is considered in concert with valuable and informative clinical data, CSC again respectfully reaffirms its previous position that the Agency should require patient experience data be included and considered throughout the drug discovery and development process.

Patients’ experiences living with, treating, and/or managing their disease provides crucial information not otherwise captured through the clinical process. The importance of patient experience data is particularly elevated with regard to collecting and including the psychosocial impact of a disease. Patient input not only informs the clinical context and provides insight to frame the assessment of benefits and risks, but it can also serve as a direct source of evidence for use in clinical studies in investigational therapies. Recognizing that patients are the foremost experts in their disease, clinical trial design, trial endpoint selection, regulatory reviews, and post-market surveillance should all include meaningful patient feedback and patient experience data. Incorporating this information into drug labeling will assist future patients, their loved ones, and their health care team to make better informed decisions.

We are particularly encouraged to see on page 1, line 41, the inclusion of both physical and psychosocial impacts of such disease or condition, or a related therapy or clinical investigation on patients’ lives as amended by the U.S. Food and Drug Administration Reauthorization Act of 2017. We look forward to working with the FDA to ensure that
this change is consistently embedded into the work of the Agency and strongly encouraged among manufacturers and other stakeholders.

**Establishing the Appropriate Background**

Proceeding on CSC’s above expressed premise that patient experience data be required to be considered in the drug discovery and development process, CSC recommends the following edits to this Draft Guidance:

- Page 2, Line 54: Add “the impact of both physical and psychosocial impacts on the patient, family members, and caregivers.”
- Page 2, Line 55: To recognize the value of perspectives provided by patients’ family members and caregivers, edit to read “…patient, family member, and caregiver perspectives…”
- Page 2, Line 55: Just as all derived clinical outcome data is valuable throughout the medical product lifecycle, so too all derived patient, family member, and caregiver perspectives are valuable throughout the medical product lifecycle. Please edit to read “…patient, family member, and caregiver perspectives are valuable in addressing…”
- Page 2, Line 58: Edit to read “…is helpful at any stage of…”
- Page 2, Line 65 and 66: To ensure patients are involved throughout the entirety of the process, edit to read “During the design and conduct of a clinical trial, gather patient input on…”
- Page 2, Line 71: Acknowledge the value of patient input by editing to read” …is informative to collect patient input…”
- Page 2, Line 75: To include the important role family members and caregivers often provide to patients in using a product, edit to read “…the information that patients, family members, and caregivers need to safely…”
- Page 3, Line 84: Edit to read “…patient experience that is developed and submitted by external stakeholders is helpful…”
- Page 3, Line 98: The importance of family members warrants their specific inclusion by editing to read, “Patients, family members, caregivers…”

CSC appreciates the FDA including a Questions and Answers section in the Draft Guidance to assist stakeholders in developing and submitting patient experience data with the Agency. Patient experience data is valuable and informative only to the extent that it is effectively developed, submitted, and considered in the drug discovery and development process. CSC recognizes the great disparity existing between different categories of stakeholders, with patients - possessing the greatest knowledge and expertise on the implications and burdens of the disease - potentially possessing minimal knowledge and expertise on how to develop and submit their patient
experience data to the Agency so that it may inform drug development and benefit future patients.

**Informing Patients and Other Stakeholders on How to Develop and Submit Proposed Draft Guidance Relating to Patient Experience Data and Other Opportunities to Help Advance Patient-Focused Drug Development**

Understanding the importance of an effective process to develop and submit patient experience data, CSC respectfully submits the following edits to the Draft Guidance:

- Page 4, Line 138: To acknowledge the premise that all patient experience data has value, insert the following, “Information obtained from patient experience data is valuable throughout the medical product lifecycle.”
- Page 4, Line 142: To assist stakeholders in identifying and maximizing the greatest potential benefit derived from patient experience data, edit to read “Is there a stage in a medical product lifecycle where patient experience data is particularly informative for a given disease area…”
- Page 5, line 189: Acknowledging that all patient experience data has value, edit to read “…that may be the most useful…”
- Page 7, Line 284: Clarify that a new docket will be opened only upon a stakeholder submitting a proposed draft guidance, as compared to stakeholders interested in submitting a proposed draft guidance, by editing to read “FDA’s Division of Dockets…”
- Page 7, Line 289: To clarify that the process following the submission of a proposed draft guidance does not end with FDA’s CDER or CBER ensuring it is sent to the relevant office(s) and/or division(s) within each Center, edit to read, “…within each Center where the proposed draft guidance will be reviewed.”

**Table 1: How Patient Experience Data Could Enhance Medical Product Development and Decision Making**

- Row “Patient registry or natural history study data”, Column “Regulators”: Edit to read “Enhance the understanding of the course of disease over time, identifying demographic, genetic, environmental, psychosocial, and other factors…”
- Row “Study report or survey data…”, Column “Patient Stakeholders”: Edit to read: “Identify burden of disease and unmet medical and psychosocial needs that warrant further scientific discussion.” Also edit row heading to read: “Study report or survey data on the therapeutic context (severity of condition and unmet medical and psychosocial need)…”
- Row “Study report or survey data…”, Column “Patient Stakeholders”: Edit to read: “Inform patients on possibilities to participate in development and validation of clinical trial endpoints, patient-reported outcomes, and patience experience data.”
Conclusion
The Cancer Support Community continues to support the FDA’s efforts to promote the collection of patient experience data throughout the drug development process and looks forward to the opportunity to collaborate with the Agency, drug manufacturers, and patient advocacy organizations to further this endeavor. CSC appreciates the prescriptive guidance offered in the Draft Guidance explaining different opportunities for how stakeholders can and should engage with the FDA early and often, a request CSC asked of the FDA in a previous comment. The edits proposed by CSC in these comments ensure that patient experience data is an integral part of the future of drug development and that patients, their family members, and caregivers are able to actively participate in this important process. We thank the FDA for the opportunity to submit these comments. As always, 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. I can be reached at efranklin@cancersupportcommunity.org or 202.650.5369.

Sincerely,

Elizabeth F. Franklin, LGSW, ACSW
Executive Director, Cancer Policy Institute
Cancer Support Community Headquarters
Cancer Support Community, Comments to Docket No. FDA-2018-D-1893: Patient-Focused Drug Development: Collecting Comprehensive and Representative Input (Guidance 1); Request for Comments (September 10, 2018).