NATIONAL COALITION FOR CANCER SURVIVORSHIP

The power of survivorship. The promise of quality care.

submitted electronically

April 29, 2016

Divisions of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

RE: Federal Register Notice FDA-2010-N-0128-0078, for Prescription Drug User Fee Act; Reopening of Comment Period

A national nonprofit organization founded by cancer survivors and focused on improving the quality of care for all cancer survivors, the National Coalition for Cancer Survivorship (NCCS) has been pleased to participate in the PDUFA (Prescription Drug User Fee Act) VI stakeholder meetings. We also appreciate this opportunity to submit comments on the PDUFA VI negotiations.

NCCS believes that each PDUFA cycle provides significant opportunities for patients. The PDUFA process can enhance the FDA's drug-approval process by improving the FDA's procedures, tools, and capabilities used to regulate treatments for increasingly complex medical problems such as cancer. We believe that PDUFA allows the FDA to continue to make the drug-approval process more efficient and to continue to implement advances in science.

As we noted in our presentation at the December 2015 stakeholder meeting, we see that PDUFA provides opportunities that are particularly important to oncology, namely the opportunity to advance the understanding of and appropriate use of adaptive clinical trials, to advance the science of conducting clinical trials for combination therapy, and to continue to advance the work in biomarkers.

We have noted with interest the FDA's attention to gathering real world evidence (RWE) to use in regulatory decision-making as well as Commissioner Califf's statements around RWE. We agree that RWE, now in its infancy, has tremendous potential to produce significant data that can help to evaluate a product's safety and efficacy.

We recognize that, as noted in the February 2016 stakeholder meeting, the FDA is seeking a greater understanding of how such data can be generated and used appropriately in the FDA's work. Because these data originate from patients, we encourage the FDA to engage systematically patients and consumers throughout these discussions from the beginning. The FDA has opportunities to solicit the views of patients in its patient-focused drug-development (PFDD) meetings, but we urge the FDA to go beyond the PFDD meetings and to engage stakeholders through meetings focused specifically on data collected as part of efforts around RWE.

Given this focus on RWE, it is worthwhile to reiterate our comments on patient-reported outcomes (PROs) made last December: that there can be tremendous benefit to including PROs, properly collected and analyzed, in the drug-development process and that PROs, properly collected and analyzed, can be immensely helpful to patients in shared decision-making. NCCS, as an organization that empowers cancer survivors to engage in their care, has long fostered shared decision-making and believes that patients must consider whatever factors are important to them in making treatment decisions, including how they will feel and function during their treatment and afterward.

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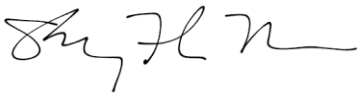
If you have any questions about our comments, please feel free to contact Christin Engelhardt, Director of Policy and Advocacy, at 301-562-2768 or cengelhardt@canceradvocacy.org.

Thank you for re-opening the comment period, as well as for the opportunity to participate in the PDUFA stakeholder meetings, and we look forward to continuing to work with the FDA.

Sincerely,



Shelley Fuld Nasso
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