

August 28, 2013

Leslie Kux,  
Assistant Commissioner for Policy  
Office of Health and Constituent Affairs  
U.S. Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993

Filed electronically at [www.regulations.gov](http://www.regulations.gov)

RE: Docket No. FDA-2013-N-0596: Lung Cancer Patient-Focused Drug Development: Public Meeting

Dear Ms. Kux,

The National Coalition for Cancer Survivorship (NCCS) applauds the FDA's efforts to seek input from patients on the drug development process. NCCS is writing to supplement my comments made during the FDA public meeting on June 28, 2013, Thank you for hosting the meeting and for considering patient input. The meeting organizers and facilitators did an excellent job of seeking the opinions and perspectives of patients and caregivers, including the panelists, audience members, and virtual attendees who were listening via the webcast. I appreciated the opportunity to serve on the panel and talk about the importance of shared decision-making and consideration of all treatment options.

While many important perspectives were presented at the meeting, including success stories of courageous survivors who have completed treatment or are currently in treatment, there were important perspectives that were missing. Obviously in a meeting such as this, it is the survivors who are now cancer free or who are doing well in their treatment who are able to participate and share their stories. Absent from the meeting was the perspective of those individuals who are actively dying of the disease and a discussion the symptoms and side effects encountered during the late stages of the disease. I spoke briefly about a former NCCS staff member, Dan Waeger, who joined NCCS as a Development Manager in 2006, a year after a diagnosis of Stage IV lung cancer. Diagnosed while in college, Dan founded the National Collegiate Cancer Foundation to provide services and support to young adults pursuing a higher education throughout their cancer treatment and beyond. Dan's experience with cancer spanned nearly four years before he died in 2009. During that time, he experienced many highs and lows, including serious side effects of treatments and late stage of the disease, such as skin irritation, lack of appetite, weight loss, persistent cough, prolonged nausea, shortness of breath, edema, and ascites. While he was grateful for the treatment options that allowed him to live nearly four years after his diagnosis, he had an ongoing fear of running out of treatment options. Dan used his experience as a survivor to increase awareness of the challenges that he and others facing a cancer diagnosis deal with on a daily basis. He honed his advocacy skills and reached beyond himself to encourage and empower others. He did not shy away from the difficult questions that accompanied his diagnosis and encouraged others to do the same.

There was much discussion during the meeting about the importance of a positive outlook, and Dan Waeger exemplified a positive attitude toward his cancer experience. Yet, as we all know, lung cancer will claim nearly 160,000 Americans this year, and the five-year survival rate across all stages is only 16%.<sup>1</sup> NCCS respectfully suggests that a positive outlook, while important to quality of life and well-being during treatment, is not sufficient – we need better treatments that successfully extend life and improve the quality of life after a diagnosis of lung cancer.



NATIONAL COALITION  
FOR CANCER SURVIVORSHIP

*The power of survivorship. The promise of quality care.*

In my comments, I talked about the personal decision of my father-in-law not to undergo treatment for lung cancer for a variety of reasons, including his current health status, the likelihood of benefit from treatment, the side effects of treatment, and access to treatment in his rural community. While his decision was the only example cited during the meeting of a patient foregoing treatment, his experience is not uncommon. A recent study by Small et.al. examined the prevalence and characteristics of individuals who received no anticancer therapy for their Stage IV solid tumors.<sup>2</sup> Of the nearly 775,000 individuals with Stage IV cancer in the National Cancer Database (NCDB) included in the study, 20.6% received no first-course therapy across several tumor types. Patients with lung cancer represented 68% of the nearly 160,000 patients who were untreated, and patients with non-small cell lung cancer (NSCLC) were most likely to be untreated. The authors note that there are multiple reasons for the lack of treatment, including co-morbidities, poor functional status, lack of access to care, and personal preference. They also observed differences in rates of no treatment by age, racial and ethnic minority status, insurance status, and income.

It is worth noting that cancers with fewer effective treatment options had higher rates of no treatment than cancers with more tolerable treatment options, and the rates of no treatment for kidney cancer decreased with the advent of vascular endothelial growth factor receptor tyrosine kinase inhibitor (VEGFR TKI) therapy as a treatment option. This point speaks to the important patient need for treatments where the benefits in terms of quantity and quality of life outweigh the significant side effects of treatment. Additionally, as the number of targeted treatments for lung cancer continue to expand, it is critical that lung cancer patients are offered the molecular diagnostic tests that might direct them to targeted therapies that represent promising treatment options. NCCS is concerned that molecular testing for lung cancer patients is not happening consistently in practice today and will advocate for the delivery of high-quality care that adheres to clinical practice guidelines regarding testing.

Thank you for the opportunity to share these additional comments.

Sincerely,

A handwritten signature in black ink, appearing to read "Shelley Fuld Nasso".

Shelley Fuld Nasso  
Senior Director of Policy

---

<sup>1</sup> American Cancer Society. Cancer Facts & Figures 2013. Atlanta: American Cancer Society; 2013

<sup>2</sup> Small, A. C., Tsao, C.-K., Moshier, E. L., Gartrell, B. A., Wisnivesky, J. P., Godbold, J. H., Smith, C. B., Sonpavde, G., Oh, W. K. and Galsky, M. D. (2012), Prevalence and characteristics of patients with metastatic cancer who receive no anticancer therapy. *Cancer*, 118: 5947–5954. doi: 10.1002/cncr.27658