



Oncology Nursing Society

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March 28, 2016

Ms. Leslie Kux
Associate Commissioner for Policy
c/o Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852
Submitted electronically via: <http://www.regulations.gov>

RE: Next Generation Sequencing-Based Oncology Panels; Public Workshop; Request for Comments (Docket No. FDA-2015-N-4990)

Dear Ms. Kux,

The Oncology Nursing Society (ONS) is a professional organization of over 35,000 registered nurses and other healthcare providers dedicated to excellence in patient care, education, research, and administration in oncology nursing. ONS members are a diverse group of professionals who represent a variety of professional roles, practice settings, and subspecialty practice areas. Oncology nurses are leaders in the healthcare arena, committed to continuous learning and leading the transformation of cancer care by advocating for high-quality care for people with cancer.

We are writing in response to your Request for Comments in connection with the Public Workshop that was held on February 25, 2016, where the development of appropriate regulatory standards for evaluation of Next Generation Sequencing-based (NGS-based) oncology panels in cancer patient management was discussed.

As FDA outlines in the notice of public workshop/request for comments, NGS-based cancer panels (laboratory panels of tests) detect mutations in tumor tissue. NGS tumor panels identify mutations that are potentially druggable targets, whether drugs exist for them now or not. These lab panels are increasingly seen as cost-effective methods to use any tumor tissue effectively and not run multiple single gene-comparing studies.

The FDA acknowledges that NGS advancements introduce challenges to the current companion diagnostic paradigm designed to assess a single pre-specified mutation associated with a therapeutic response. One concern raised by clinicians is that the results gleaned from these panels of mutation findings may be

ahead of our therapeutic abilities, since mutations identified may not yet have a therapeutic response available.

We believe the FDA's approach to performance characteristics of NGS-based oncology panels to include variants that are intended to be used as companion diagnostics, as well as other variants that may be used for alternative therapeutic management of patients must take into consideration that alternative therapeutic responses may, in fact, not exist. The regulatory standards must recognize this eventuality, and therefore, help to encourage safe yet rapid industry response to new discoveries. The gap between unidentified mutations and the desire to spur therapeutic responses should also inform FDA's expedited consideration of new treatments of the newly-identified mutations, and the desire to maintain flexibility that insures expeditious integration of new therapies into the NGS regulatory regime.

We applaud FDA's effort to solicit input on strategies for establishing performance characteristics for NGS-based oncology panels for rare variants across tumor types, follow-on companion diagnostic claims, and post-approval assay modifications. We interpret this as an inherent recognition that the NGS-based technology has enormous potential to create life-saving breakthroughs for cancer patients, a potential we all hope our regulatory system has the foresight to harness effectively.

We appreciate the opportunity to submit comments in connection with your public workshop and obtain feedback on analytical and clinical validation approaches for NGS-based oncology panels. Should you have any questions regarding our comments, please contact Alec Stone, MA, MPA, ONS Director of Health Policy, at astone@ons.org. We look forward to engaging in an ongoing dialogue to address issues of importance to our cancer patients and, most importantly in this discussion, ways in which we can enhance cancer patient management.

Sincerely,

The Oncology Nursing Society