



## Oncology Nursing Society

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March 14, 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: [www.regulations.gov](http://www.regulations.gov)

**RE: Notice; Establishment Of Docket; Request for Comments; “Clinical Outcome Assessment Compendium” (Docket No. FDA-2015-N-5106)**

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 the Request for Comments on the pilot “Clinical Outcome Assessment Compendium” (COA Compendium). ONS applauds the FDA's focus on measures that capture outcomes that "are important to patients" in clinical trials and efforts to foster patient-focused drug development. ONS supports the benefits of a standardized approach to assessment of patient outcomes, for which the compendium would be an asset. An opportunity to view the instrument to be used, as part of the pilot compendium, would benefit researchers and garner support for its use.

We believe outcomes measures that capture the patients needs, values and goals should be incorporated into all clinical trials as a part of outcomes measurement. ONS's members are uniquely aware of those indices that would matter most to patients with cancer. ONS is uniquely qualified to provide input into outcomes measures specific to outcomes that matter most to patients with cancer and their families.

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We appreciate the opportunity to submit comments on the FDA's pilot “Clinical Outcome Assessment Compendium” and welcome any opportunity to assist with the development of meaningful patient-focused outcomes measures in conjunction with this FDA initiative. Should you have any questions regarding our comments, please contact Alec Stone, MA, MPA, ONS Director of Health Policy, at [astone@ons.org](mailto: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 improve patient-centered outcome measures and breakthrough drug developments for cancer patients.

Sincerely,

The Oncology Nursing Society