

The Cancer Policy Institute *at the*   
**CANCER SUPPORT COMMUNITY**  
*Uniting The Wellness Community & Gilda's Club Worldwide*

May 1, 2017

Representative Leonard Lance  
426 Cannon HOB  
Washington, DC 20515

Representative Diana DeGette  
2111 Rayburn HOB  
Washington, DC 20515

Dear Representative Lance and Representative DeGette,

We write to you today as Friends of the Cancer Policy Institute, a coalition of professional and advocacy organizations working to ensure that all people impacted by cancer are empowered by knowledge, strengthened by action and sustained by community.

The purpose of this outreach is to lend support for the work being done to incorporate psychosocial distress screening across the cancer care continuum, and to specifically support H.R. 2244 the Patient Experience in Research Act of 2017. This legislation directs the Secretary of Health and Human Services to carry out a pilot project under which no more than three sponsors agree to evaluate the psychological and social distress experienced by patients participating in a clinical trial.

The introduction of this act is very timely as the Food and Drug Administration (FDA) has an unprecedented opportunity with the reauthorization of the Prescription Drug User Fee Act (PDUFA) as well as new requirements for the FDA as outlined in the 21<sup>st</sup> Century Cures Act to incorporate the recommendations of leading provider, academic and consumer driven organizations to ensure cancer patients receive psychosocial distress screening and if necessary, follow-up care as part of the clinical trial process. Data published by Barbara Andersen, PhD, demonstrates that psychosocial distress screening along with follow-up care is associated with an improvement in patient outcomes (quality of life and survival rates) and should therefore be offered to individuals participating in a clinical trial.

As has been documented across a number of esteemed organizations including the Institute of Medicine, "[t]oday, it is not possible to deliver good-quality cancer care without using existing approaches, tools, and resources to address patients'

psychosocial health needs.” Additionally, as the comprehensive care conversation evolves and becomes more inclusive of the patient, it is no longer acceptable to limit patient assessments to disease symptoms, treatment side effects and physical functioning. Additional data collected through distress screening (e.g., concerns related to disruption of work/family life [due to the regimen], concerns related to nutrition, financial impact and others) would provide meaningful feedback through the patient voice in real time about issues that may not be identified through the current measures.

The recommendations of the Institute of Medicine and the work of Dr. Andersen and others has recently been supported through the language seen in the 21st Century Cures Act that requires the FDA to publish “patient experience data” that includes “the impact of such disease or condition, or related therapy on patients’ lives.” The Cancer Support Community and Friends of the Cancer Policy Institute thank you for your leadership on this important legislation to ensure progress on the inclusion of patient experience data to more fully understand the full impact of interventions on trial participants.

Thank you for your consideration of our request. If you would like to get in touch with the Cancer Policy Institute, please contact Kristen Santiago at 202-552-5091 or at [Kristen@CancerSupportCommunity.org](mailto:Kristen@CancerSupportCommunity.org).

Sincerely,

Academy of Oncology Nurse & Patient Navigators  
American Cancer Society Cancer Action Network  
American College of Surgeons Commission on Cancer  
Association of Oncology Social Work  
*CancerCare*  
Cancer Support Community  
Friends of Cancer Research  
FORCE: Facing Our Risk of Cancer Empowered  
International Myeloma Foundation  
ICAN, International Cancer Advocacy Network  
Leukemia & Lymphoma Society  
LIVESTRONG Foundation  
Lung Cancer Alliance  
Musella Foundation for Brain Tumor Research & Information, Inc.  
National Alliance on Mental Illness  
National Organization for Rare Disorders  
Oncology Nursing Society  
Prevent Cancer Foundation

## References

Adler, N.E., Page, A.E.K. (2008). Cancer care for the whole patient: Meeting psychosocial health needs. Institute of Medicine (IOM). Washington, DC: The National Academies Press.

Andersen, B.L., Thornton, L.M., Shapiro, C.L., Farrar, W.B., Mundy, B.L., Yang, H.C., and Carson, W.E. (2010). Biobehavioral, immune, and health benefits following recurrence for psychological intervention participants. *Clinical Cancer Research*; 16(12); 4490.