

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

January 31, 2017

Janet Woodcock, M.D.
Director, Center for Drug Evaluation and Research
Food and Drug Administration
10001 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Woodcock,

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. This is very timely as the 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 21st 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.

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.

In previous communications, we have forwarded data published by Barbara Andersen, PhD, in 2010 which demonstrated that psychosocial distress screening along with follow-up care is associated with an improvement in patient outcomes (quality of life and survival rates). 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 would like to partner

with the FDA on the development of a pilot study and guidance on how to collect this “patient experience data” given our expertise.

As Friends of the Cancer Policy Institute, we ask you to use your leadership and your regulatory authority to make progress in this important area, and we look forward to supporting you in any way that we can.

Thank you for your consideration of our request. If you would like to get in touch with our organizations, please contact Kristen Santiago at 202-552-5091 or at Kristen@CancerSupportCommunity.org.

Sincerely,

Cancer Support Community

cc: Francis Collins, Director, National Institutes of Health
Stephen Ostroff, Acting Commissioner, Food and Drug Administration
Richard Pazdur, M.D., Oncology Center of Excellence Director, Food and Drug Administration
Sen. Lamar Alexander (TN), Chair, Senate Health, Education, Labor and Pensions Committee
Rep. Greg Walden (OR), Chair, House Energy and Commerce Committee

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.