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

December 2, 2015

The Honorable Sylvia Mathews Burwell
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Burwell,

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. Each of our organizations are eager to work with you to ensure that the federal government is promoting best practices with respect to psychosocial oncology care across its operating divisions and in particular, at the NIH and FDA. HHS has an unprecedented opportunity to incorporate the universal recommendations of leading provider, academic and consumer driven organizations to ensure cancer patients receive distress screening and if necessary, follow-up care, when diagnosed with cancer. (Distress screening identifies those issues that can negatively impact treatment and outcomes.)

We believe that an important first step in this effort is to direct the National Institutes of Health (NIH) and the Food and Drug Administration (FDA) to develop standards and protocols in clinical trials to screen patients for psychosocial distress and provide them with follow-up or supportive care, if needed. By doing so, we believe you will **improve patient outcomes**

Research published in a 2008 Institute of Medicine report entitled, "Cancer Care for the Whole Patient" shows that up to 43 percent of people with cancer experience psychosocial distress, which negatively impacts both their overall quality of life and long term survivorship. Further, a 2010 study by Barbara Andersen, PhD, demonstrated that when patients participated in a bi-weekly support group for one year, they experience a reduced risk for breast cancer recurrence and a reduced risk of dying from breast cancer if they did have a recurrence. Most impressive, however, is that those participating in a support group lived a full 1.3 years longer than their counterparts who did not participate.

This compelling body of data led the American College of Surgeons Commission on Cancer (CoC) to require its 1,400 hospitals and cancer centers, which see 3 out of every 4 cancer patients, to screen patients for distress and provide follow up care beginning this past January. Patients who enroll in clinical trials, including those funded by NIH, are only guaranteed psychosocial support if that trial happens to be at a CoC-accredited facility.

Requiring distress screening in clinical trials will also improve the efficiency of the trials process. A recent study published by the Tufts Center for the Study of Drug Development noted several indicators of concern related to trends in clinical trials. In particular, the study identified:

- An increased burden of procedures per trial protocol of 65%*
- An increased length of clinical trial days of 70%*
- A decrease in clinical trial enrollment rate by 21%*
- A decrease in clinical trial retention rate by 30%*

*1999 compared to 2005

A study presented by the Cancer Support Community in December 2014 explored the attitudes and beliefs of patients with metastatic breast cancer regarding clinical trials. In addition to having significant misperceptions about clinical trials generally (e.g., fear of being assigned to a placebo, fear of side effects, etc.), a full 22 percent of patients indicated that they would not be able to fulfill trial requirements due to logistical barriers such as transportation. In cancer, where only 3 percent of eligible patients enter a clinical trial, the loss of 22 percent at the beginning of the process is a significant issue. By addressing these issues through distress screening and support services, there will be dramatic improvements in our ability to recruit and retain patients in trials.

Furthermore, the use of a validated distress screening tool can help address the lack of adequate collection of patient reported outcomes as a part of real-time drug development. In the cancer community, the recognition of this deficit became even more urgent on June 22 with the release of the American Society of Clinical Oncology (ASCO) Value Framework. The framework assesses new treatment options in comparison to older treatment options with the issuance of a score to be used in treatment decision-making. In the framework, there is no consideration of low-grade, chronic side effects having an impact on patients, despite overwhelming evidence of the challenges they pose. When asked about the omission, Dr. Lowell Schnipper, on behalf of ASCO, indicated that the decision was due to the "global deficiency" of not collecting patient reported outcomes data as a part of the drug development process, but noted that this is a deficiency we must correct.

Secretary Burwell, you have the opportunity to correct this global deficiency. We urge you to direct the NIH to develop clinical trial protocol standards that include routine screening for social and emotional distress, the provision of appropriate supportive care, and guidance for documentation of patient reported outcomes as a routine part of the clinical trial process. In addition, we urge you to work with the FDA to encourage drug and device manufacturers to develop product development plans and data sets that include routine screening for social and emotional distress, the provision of appropriate supportive care and guidance for documentation of patient reported outcomes as a routine part of the clinical trial process.

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 have any questions or would like to get in touch with our organizations, please contact Rob Goldsmith at 202-650-5365 or at rob@cancersupportcommunity.org.

Sincerely,

Association of Community Cancer Centers
Bladder Cancer Advocacy Network
Cancer Care
Cancer Support Community
C-Change
Facing Our Risk of Cancer Empowered
Fight Colorectal Cancer
Friends of Cancer Research
International Myeloma Foundation
The Leukemia and Lymphoma Society
Lung Cancer Alliance
The Max Foundation
Musella Foundation
National Patient Advocate Foundation
Oncology Nursing Society
Prevent Cancer Foundation

cc: Francis Collins, Director, National Institutes of Health
Stephen Ostroff, Acting Commissioner, Food and Drug Administration

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