CANCER LEADERSHIP COUNCIL

A PATIENT-CENTERED FORUM OF NATIONAL ADVOCACY ORGANIZATIONS ADDRESSING PUBLIC POLICY ISSUES IN CANCER

January 20, 2006

Via Electronic Filing and Telecopy

Ernest T. Hawk, M.D., M.P.H.
Director
Office of Centers, Training and Resources
National Cancer Institute
6116 Executive Blvd. - #700
Bethesda, Maryland 20892

Dear Dr. Hawk:

The undersigned organizations, representing cancer patients, physicians, and researchers, appreciate the opportunity to comment on the mission and responsibilities of the Translational Research Working Group (TRWG). We applaud the National Cancer Institute (NCI) for convening this panel and offer several suggestions related to the TRWG membership and the process for soliciting input regarding the group's work.

Process for Soliciting Written Comments

We commend the leadership of NCI and TRWG for establishing a process for the submission of comments from interested individuals and organizations regarding the panel and its work. However, we recommend that the comment procedures be revised to encourage a more public exchange of advice and opinions. The advantages that might result from keeping all comments confidential – including the possibility that commenters will be more candid than if their comments are published – are greatly outweighed by the benefits of an open and public exchange of views. Moreover, it is unclear by what authority NCI would be able to safeguard the confidentiality of comments submitted to it as a public agency, thus suggesting that potential commenters may be given an unrealistic sense of security regarding their comments.

We suggest that comments be available to the public, by providing access to hard copies of comments in a central location and also by ensuring access to electronic copies on the TRWG website. Stakeholders will be interested in the concerns and interests of others, and public availability of comments will foster an open dialogue about the TRWG and its mission.

Contact: One Metro Center • 700 12th Street N.W. • Suite 900 • Washington, D.C. 20005

Phone: 202-508-4600 • Fax: 202-508-4650 • www.cancerleadership.org

Procedures for Selection of Working Group Members and Roundtable Participants

Members of the patient advocacy community have experienced significant confusion about the procedures that NCI would follow in selecting members of the TRWG. Some understood that there would be a well-defined application process, in which the standards for selection for TRWG membership and a deadline for submission of applications would be published. The appointment of TRWG members absent notice regarding the process for selecting members was a surprise to many advocates.

We recommend below that the membership of the TRWG be expanded to include representatives of several different interests. In addition to specific proposals regarding TRWG membership, we suggest that NCI and TRWG leadership develop and make public the standards that will be employed in choosing those who will participate in the Roundtable meetings. As there was a lack of clarity regarding the naming of TRWG members, there is now uncertainty regarding participation in the Roundtable meetings. Transparency regarding the standards for Roundtable participation is critical to encouraging receptivity in the cancer community to the TRWG recommendations.

Expansion of the TRWG Membership

The TRWG, with current members, is a large group in which productive and creative discussion and debate may be difficult. Despite the size of the panel, however, we recommend that careful consideration be given to the addition of several members in these categories:

- ***Patient advocates.*** The inclusion of only three patient representatives on a panel of 60 is inadequate to guarantee that the patient or survivor voice is heard and that the diversity of the patient community is conveyed. More patient advocates should be added to the panel. Supplementing the patient advocate membership of TRWG will ensure that the diverse perspectives of survivors are communicated. In addition to bringing the viewpoint of the ultimate "consumer" of translational research, patient advocates have other experiences and expertise to offer the TRWG. We note in particular that a number of patient-driven organizations are significant funders of translational research and can share the knowledge derived from administering these programs.

- ***Representatives of "rare cancers."*** The TRWG includes some researchers whose work focuses on cancers of rare incidence, but we suggest that the membership be expanded to include more researchers with knowledge and experience related to rare

cancers, and that the additional patient advocates who are named to the panel include those knowledgeable about rare cancers. Without a greater number of researchers and patient advocates with a commitment to rare cancers, we are concerned that there will be insufficient attention paid to the special challenges associated with research on these cancers.

- ***Industry representatives.*** We identify two representatives of the pharmaceutical industry on the TRWG. Because industry is an important partner in the translational research enterprise and because there is significant diversity among industry players, we are skeptical that two representatives from pharmaceutical companies can fully and adequately represent industry. We propose that additional industry members, including those from biotechnology companies, be named to the TRWG to ensure that the industry's translational research views will be more appropriately conveyed.

Because the work of the TRWG is of great importance to the entire community of cancer patients, physicians, and researchers, it is critical that the panel represent the broadest cross-section of the community and include those who can articulate the needs of the medically underserved. In re-evaluating the membership of the TRWG, we urge the TRWG and NCI leadership to assure that the membership reflects the diversity of the cancer community and American society.

Specialized Programs of Research Excellence (SPOREs)

We understand that the charge of the TRWG is broad and includes an evaluation of the entire translational research portfolio. As the group moves forward with its evaluation of the NCI translational research effort, we urge that special attention be paid to the role of the Specialized Programs of Research Excellence (SPOREs) in the translational research process. In particular, we suggest that the SPOREs be carefully considered for features or advantages they possess that may not be replicated in other research funding mechanisms.

*****

The TRWG has significant responsibility for evaluating the translational research program at NCI, and the membership of the group and its procedures for deliberation are critical to its success. We offer the suggestions above to guarantee that the TRWG continues its work while enjoying the support and confidence of the cancer community.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
American Society for Therapeutic Radiology & Oncology
Bladder Cancer Advocacy Network
Cancer Research and Prevention Foundation
The Children's Cause for Cancer Advocacy
Fertile Hope
International Myeloma Foundation
Kidney Cancer Association
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Prostate Cancer Coalition
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
The Susan G. Komen Breast Cancer Foundation
Us TOO International Prostate Cancer Education and Support Network
Y-ME National Breast Cancer Organization

cc: Dr. Andrew von Eschenbach
Dr. John Niederhuber