*Joan Darling*
*Children's Oncology Group - Patient Advocacy Committee*
*611 Hazelwood Drive*
*Lincoln, NE 68510*

June 30, 2011

**VIA US MAIL**

Harold Varmus, M.D., Director
National Cancer Institute
31 Center Drive, MSC 2590
Building 31 – Room 11A48
Bethesda, MD 20892

**VIA Email**

(harold.varmus@nih.gov)

James H. Doroshow, M.D., Deputy Director
National Cancer Institute
31 Center Drive, MSC 2440
Building 31 – Room 3A44
Bethesda, MD 20892

(james.doroshow@nih.hhs.gov)

**RE: Implementation of a National Cancer Clinical Trials System for the 21st Century: COG Patient Advocate Recommendations for Funding Opportunity Announcement and Clinical Trials Group Reconfiguration**

Dear Dr. Varmus and Dr. Doroshow:

We are writing to you as research patient advocates working in the Children's Oncology Group to express our thoughts and concerns about the Funding Opportunity Announcement and the related reconfiguration of the NCI clinical trials group (together, the "Implementation"). The NCI-funded Cooperative Group system is a crucial resource and key to continuing to advance new and better treatments to treat cancer.

Although the Children's Oncology Group will not be directly impacted by the Implementation, we are keenly aware that ultimately any slowing of progress in the adult clinical trials could adversely affect clinical research in children. Therefore, although we understand and applaud the goals of the Implementation, we are concerned that any remake of the adult Clinical Trial System not hobble the reconfigured Cooperative Groups and not distract them from developing new cures for cancer.

The composition of the cancer advocates in COG includes cancer survivors, parents and loved ones of cancer patients, nurses and ethicists. Some of us did experience the consolidation of the four legacy pediatric cancer research organizations into COG and hope that lessons from that experience can be applied to the Implementation.

We respectfully advance ten recommendations concerning the Implementation:

1. Incorporate into the Implementation tangible patient and scientific outcomes as primary objectives of the Implementation. We would expect those objectives to include:

    - The development of all key clinical trials;
    - Maximizing patient enrollment in clinical trials;
    - Special development of clinical trials for rare tumors.
    - Increased diversity in the participation in clinical trials, particularly under-represented minority communities.
    - Faster development of trials and the careful review of procedural hurdles that slow approval.

2. Establish instrumentation, transparency, and accountability (including, clear metrics with targets, timeframes and responsible parties) into the management of all aspects of the Implementation.

3. Define what constitutes success of the Implementation in terms of concrete objectives and timeframes and how they will be managed and achieved.

4. Avoid allowing the timetable for the Implementation to precede rational design and planning. If the design is not vetted or the metrics to manage the Implementation are not in place, suspend implementation dates until there is a solid design and clear metrics to guide the Implementation.

5. Respond quickly with needed course corrections where appropriate; adopt flexibility and transparency in the design of the Implementation and incorporate consultation with and participation on an ongoing basis by the Cooperative Group leadership, PIs and other and members of the Cooperative Groups including patient advocates at every stage of the Implementation process. Continue to consult with the past and present leaders and membership of the Children's Oncology Group and the NCI staff who dealt with the COG consolidation to determine what worked best (and what did not) in that earlier process.

6. Incorporate milestones with go/no-go decision points and pilot programs for the more challenging elements of the new operating models.

7. Support funding and logistical support to the consolidation of the Cooperative Groups contemplated by the Implementation, including assistance with mediating conflict and organizational integration, with focus on steps to ensure that any interruption in Cooperative Group core functions caused by consolidation is mitigated and that the disruption of new and ongoing clinical trials is minimized.

8. Clarify the plans to address IOM recommendations relative to NCI's role in the clinical trials enterprise

9. Incorporate enforcement of NIH Policy and Guidelines on the Inclusion of Women and Minorities in Clinical Research as prescribed in the NIH Revitalization Act of 1993, PL 103-43 into the Funding Opportunity Announcement and all aspects of the Implementation.

10. Enlist the cooperative group advocates as full partners in the development of the Implementation, in the reconfiguration of the cooperative groups and in the transformed groups.

Note that except for Recommendations 5 and 7, and for the objectives in Recommendation 1, we have adopted the foregoing Recommendations in whole or in part from the *Cooperative Group Advocates' Public Comment Regarding Reconfiguration of the Cooperative Group Program*, dated June 30, 2011, addressed to Dr. Varmus and Dr. Doroshow and executed by over 60 adult patient advocates.

We appreciate your consideration of these recommendations, respectfully request that they be included in the public comments on the development of the Funds Opportunity Announcement and the reconfiguration, and that you consider them in the development of the Implementation.

Sincerely,

*Joan Darling, Ph.D.*

Joan Darling, Ph.D., Chair, Children's Oncology Group Patient Advocacy Committee

*John Mussman, Esq.*

John Mussman, Esq., Children's Oncology Group Patient Advocate
COG Representative to Coalition of National Cancer Cooperative Groups

*Rebecca Pentz, Pd.D.*

Rebecca Pentz, Ph.D., Children's Oncology Group Patient Advocate
COG Representative to Coalition of National Cancer Cooperative Groups

*Jay B. Long, Esq.*

Jay B. Long, Esq., Children's Oncology Group, Patient Advocate

*Anne Lown*

Anne Lown, Children's Oncology Group, Patient Advocate

*Peggy Kulm, RN, MA*

Peggy Kulm, RN, MA, Children's Oncology Group, Patient Advocate

cc: Peter C. Adamson, M.D., Chair, COG, Patient Advocacy Group
Sharon B. Murphy, M.D., Institute of Medicine
Malcolm A. Smith, M.D., Ph.D., Assoc. Branch Chief for Pediatric Oncology, NCI
Ms. Gwen Darien, Chair, NCI DCLG
Shannon Bell, M.D., Director, Office of Advocacy Relations, NCI
Gregory H. Reaman, M.D., Assoc. Director, Office of Oncology Drug Products, OND, CDER, FDA