CANCER LEADERSHIP COUNCIL

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

November 21, 2012

Jeffrey Zients
Acting Director and Deputy Director of Management
The Office of Management and Budget
725 17th Street, N.W.
Washington, D.C. 20503

Dear Mr. Zients:

The undersigned organizations represent cancer patients, physicians, and researchers who look forward to continued innovation in the development of diagnostic tests that yield precise information about cancer diagnosis and permit appropriate targeting of treatment. If cancer patients and their physicians are to make life-changing decisions on the basis of diagnostic tests, they must be assured that such tests are reliable and provide clinically meaningful information.

For decades, the standards for introduction of new technology to patients and their physicians have been different for tests that are subject to review by the Food and Drug Administration (FDA) and tests that are considered laboratory-developed tests, which are subject to Clinical Laboratory Improvement Act (CLIA) standards. However, over the years the number, complexity, and impact on health care decisions of LDTs have increased, and the differences between FDA-reviewed tests and LDTs have become less clear. In addition, cancer patients have in recent years suffered harm from LDTs that did not provide the accurate and meaningful information that was promised.

In recognition of the importance of diagnostic tests in patient care, FDA has worked for many years on standards for the evaluation of LDTs. After such a length of time, the draft guidance on these standards should be published for public comment and advice without further delay. We believe that FDA review standards are intended to reassure patients on the reliability and usefulness of diagnostic tests and set clear parameters for developers of new tests. We offer no comment on specific standards at this time but look forward to the opportunity to comment upon release of the draft guidance.

We urge prompt release of draft guidance related to LDTs, with appropriate time for public comment. Many of the undersigned have previously participated in public

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meetings on this topic and have otherwise offered our advice on LDTs, and we stand ready to participate in a public comment period.

Sincerely,

CANCER LEADERSHIP COUNCIL

American Society for Radiation Oncology
American Society of Clinical Oncology
Bladder Cancer Advocacy Network
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
International Myeloma Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
Multiple Myeloma Research Foundation
National Coalition for Cancer Survivorship
National Lung Cancer Partnership
Ovarian Cancer National Alliance
Pancreatic Cancer Action Network
Sarcoma Foundation of America
Us TOO International Prostate Cancer Education and Support Network

cc: The Honorable Kathleen Sebelius
Secretary
Department of Health and Human Services

Margaret Hamburg, M.D.
Commissioner
Food and Drug Administration

Jeffrey E. Shuren, M.D., J.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration