

# CANCER LEADERSHIP COUNCIL

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

June 17, 2016

Nancy Beck, PhD  
Acting Deputy Director  
Reagan-Udall Foundation for the FDA  
1025 Connecticut Avenue, NW  
Suite 1000  
Washington, DC 20036

Dear Dr. Beck:

The undersigned organizations, representing cancer patients, providers, and researchers, are writing to offer comments regarding the Draft Project Proposal for the Expanded Access Navigator for Individual Patient Access. Many of us have direct experience with the request process for individual patient access to investigational drugs. We have confronted this process as patients, parents, treating physicians, and cancer drug developers.

Patients and treating physicians will be assisted by the guidance documents on expanded access, including the guidance document for completing Form FDA 3926 for expanded access requests, released recently by the Food and Drug Administration (FDA). In addition, revisions to FDA educational materials and the FDA website related to expanded access will benefit patients and physicians. However, these revised and refined documents do not provide patients and treating physicians information regarding an element of the process that is often the most difficult, requesting the consent of the drug sponsor for access to the investigational agent.

Patients and treating physicians would benefit from a reliable source of information on manufacturers' policies and procedures related to individual patient expanded access and points of contact for manufacturers. Patients seeking access to investigational agents would be aided significantly if the Reagan-Udall Foundation assumed this informational role. We understand that the Reagan-Udall Foundation would only be providing information and would not engage in any efforts to influence manufacturer policies on expanded access.

We offer this additional advice about the Expanded Access Navigator proposal:

- The information provided through the Expanded Access Navigator will only be useful if it is fully up-to-date. If patients and physicians are provided out-of-date information, including manufacturer contact information, that will undermine the usefulness and credibility of the program.

- Although patients and physicians increasingly utilize and rely on online resources, we urge that the Expanded Access Navigator program also include a call center. When patients and physicians are seeking single patient access to investigational agents, eliminating all barriers to reliable information is necessary. A call center should be part of this effort to provide timely access to reliable information.
- The use of the term “navigator” may lead to confusion. A number of cancer organizations and health cancer institutions have navigators to help patients successfully manage their cancer care journey. In addition, navigator programs have been established to assist consumers in the purchase and utilization of health insurance available through Affordable Care Act exchanges. To avoid confusion, we urge a different term for the expanded access program.
- A successful Expanded Access assistance program with the attributes we have identified above will only be possible with an adequate and predictable source of funding. The assistance program should not be launched, absent this assurance of funding.

We appreciate the opportunity to comment on the Expanded Access Navigator program.

Sincerely,

Cancer Leadership Council

*CancerCare*  
Cancer Support Community  
The Children's Cause for Cancer Advocacy  
Fight Colorectal Cancer  
International Myeloma Foundation  
Kidney Cancer Association  
The Leukemia & Lymphoma Society  
**LIVESTRONG** Foundation  
Lymphoma Research Foundation  
National Coalition for Cancer Survivorship  
National Patient Advocate Foundation  
Prevent Cancer Foundation  
Sarcoma Foundation of America  
Susan G. Komen