CANCER LEADERSHIP COUNCIL

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

March 13, 2018

The Honorable Paul Ryan
Speaker
House of Representatives
H-232, The Capitol
Washington, DC 20515

The Honorable Nancy Pelosi
Minority Leader
House of Representatives
H-204, The Capitol
Washington, DC 20515

Dear Speaker Ryan and Leader Pelosi:

The undersigned cancer organizations, representing cancer patients, health care professionals, and researchers, are writing to express serious reservations about the latest version of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act, released on March 10, 2018. We oppose the latest version of right to try legislation because it removes the Food and Drug Administration (FDA) from approval and consultation in the expanded access process, a change that is not in the best interest of people with cancer.

Our organizations have over many years sought to improve access to investigational agents while still protecting the research, development, and regulatory review of new agents. We have focused on improvements to the expanded access process, better communication about expanded access to physicians and patients, and more transparency from drug developers about their policies on expanded access. These enhancements in the process – and some efforts still underway or in implementation phase – have made a substantial difference in how patients obtain access to investigational agents.

As we have sought improvements in the process, we have maintained that FDA should remain a part of the expanded access process. The judgment of the agency about patient access to investigational agents is critical to protecting patients and ensuring them appropriate access to investigational agents.

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In fact, FDA approves virtually all the expanded access requests that are presented to the agency. The agency is not the obstacle to patient access to investigational agents. If there are problems in submitting requests to the agency, those problems might be addressed through even more intensive education and outreach. Expanded access to investigational agents may be impeded by the decisions of drug developers attempting to complete their development programs. Right to try legislation will not address the decisions that drug developers make regarding expanded access.

We oppose the latest version of the right to try legislation because it makes a hollow promise to patients that, by removing FDA from the expanded access process, they will be assured access to investigational agents. And by removing FDA from the expanded access process, the legislation eliminates important protections for patients.

We urge that the House reject the right to try legislation.

Sincerely,

Cancer Leadership Council

American Society of Clinical Oncology
Cancer*Care*
The Children's Cause for Cancer Advocacy
Fight Colorectal Cancer
Hematology/Oncology Pharmacy Association
International Myeloma Foundation
The Leukemia & Lymphoma Society
Lymphoma Research Foundation
National Coalition for Cancer Survivorship
Prevent Cancer Foundation
Sarcoma Foundation of America
Susan G. Komen

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