May 21, 2018

The Honorable Paul Ryan Speaker United States House of Representatives H-232, The Capitol Washington, DC 20515 The Honorable Nancy Pelosi Minority Leader United States House of Representatives H-204, The Capitol Washington, DC 20515

Dear Speaker Ryan and Leader Pelosi:

The undersigned cancer organizations, representing patients, physicians, other health professionals, and researchers, write to express opposition to House consideration of the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act (S. 204).

Our organizations have in recent months expressed serious reservations about Right to Try legislation, because we were concerned that the measures could expose patients to harm unnecessarily. The current Food and Drug Administration expanded access program results in approval of virtually all requests for access to unapproved therapies, so removing the agency from the review of such requests is not necessary. The barriers to access to unapproved therapies do not relate to FDA action on requests. Therefore, limiting FDA review will not ensure access to experimental therapies, as suggested by Right to Try proponents. Removing FDA from oversight of the patient requests could put patients at risk due to unsafe and ineffective experimental therapies.

Despite our fundamental misgivings about the Right to Try legislative effect, we have acknowledged that the House or Representatives-passed version of the bill (H.R. 5247) incorporated some patient safeguards including more robust informed consent requirements, FDA oversight of the process, and a more well-defined definition of eligibility for the pathway to unapproved therapies.

The plan of the House of Representatives to consider the Senate-passed bill and essentially abandon its work in strengthening the Right to Try legislation is not in the best interests of the cancer patients and health care professionals we represent. This step moves in exactly the wrong direction.

We urge the House to withhold action on S. 204, the Senate-passed Right to Try bill, and instead stand by the current expanded access program that balances the demands of patients for access to unapproved therapies and the responsibility of FDA to protect patient safety.

Sincerely,