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March 12, 2018

The Honorable Paul Ryan
Speaker
U.S. House of Representatives
H-232, The Capitol
Washington, D.C. 20515

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
H-204, The Capitol
Washington, D.C. 20515

Dear Speaker Ryan and Leader Pelosi:

On behalf of the International Society for Stem Cell Research (ISSCR), the leading professional organization for stem cell science and regenerative medicine, I am writing to express opposition to the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018.” While there have been several improvements to the Senate-passed Right to Try Act, this legislation would put patients at risk and undermine the effective FDA Expanded Access Program, already in place, that gives seriously ill patients access to experimental treatments.

Stem cell science and regenerative medicine are central to this issue, as they hold enormous potential to yield new treatments for diseases that currently have no cure, including Parkinson’s disease, multiple sclerosis, ALS, and diabetes. This legislation will cause long-term harm to this nascent field and expose patients to unnecessary risk by facilitating the dissemination of therapies that have not been proven to be safe or effective.

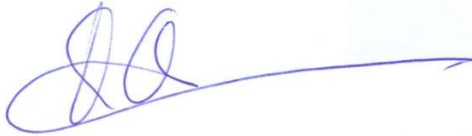
Patients understandably seek experimental therapies when they have no other treatments for incurable diseases. With the FDA’s existing Expanded Access Program, also known as Compassionate Use, patients are able to access experimental treatments through a process that provides important checks and balances to ensure patient safety, facilitates drug development, and preserves the integrity of clinical trials.

Rather than improving the existing Expanded Access Program, the proposed legislation would bypass it, and weaken the ability of the FDA to protect patients. The bill’s supporters claim this will encourage manufacturers to make more experimental treatments available to patients. However, major manufacturers have indicated that they support maintaining FDA’s role in evaluating the requests for access to investigational products.

The proposed Right-to-Try legislation would provide a route for snake-oil salesmen to evade FDA regulation. The program already in place shows there is no need for new legislation—particularly not legislation that would put patients at unnecessary risk. If passed, this legislation would embolden unscrupulous actors selling unproven and scientifically dubious therapies to patients. A number of Americans have already been blinded or paralyzed from unproven stem cell treatments, some of which were marketed in a way that caused patients to believe they were participating in legitimate clinical trials.

For these reasons, the International Society for Stem Cell Research opposes the “Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2018.” The ISSCR supports maintaining and strengthening the FDA’s role in regulating patient access to new treatments to protect the health and welfare of patients, ensure the integrity of clinical trials, and provide a clear path for new products to be developed and tested for use in patients.

Sincerely,

A handwritten signature in blue ink, consisting of a stylized 'H' and 'C' followed by a long horizontal line that tapers to a point on the right.

Hans Clevers, MD, PhD
President, ISSCR
Professor of Molecular Genetics at Hubrecht Institute
Research Director at the Princess Maxima Center for Pediatric Oncology