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Dear Members of the United States House of Representatives:

Public Citizen, a consumer advocacy organization with more than 400,000 members and supporters nationwide, respectfully urges you to oppose S. 204, the "Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017," which was passed by the Senate on August 3, 2017. Importantly, although H.R. 5247 — the House of Representatives-passed version of this legislation — has significant flaws that would endanger patients, it nevertheless would provide substantially stronger safeguards for patients who would receive investigational drugs under the Right-to-Try pathway than those provided by S. 204.

Of note, in his October 3, 2017, testimony before the House of Representatives' Subcommittee on Health of the Committee on Energy and Commerce, Dr. Scott Gottlieb, Commissioner of Food and Drugs, expressed serious reservations regarding several provisions of S. 204 and recommended changes to better protect patients. Many of these changes were incorporated into H.R. 5247.

In particular, the following are key differences between H.R. 5247 and S. 204:

- H.R. 5247 would appropriately limit the patient population eligible for the Right-to-Try pathway to those who have a stage of disease or condition in which there is a reasonable likelihood that death will occur within a matter of months or a disease or condition that would result in significant irreversible morbidity that is likely to lead to severely premature death. In contrast, the eligible patient population under S. 204 would be much more expansive, encompassing those who have been diagnosed with a life-threatening disease or condition.

- H.R. 5247 would require a much more robust informed consent process that includes the same elements of informed consent required for a clinical trial and use of a written consent form that has been reviewed and approved by an institutional review board. S. 204 lacks these essential informed consent requirements.

- H.R. 5247 would require the sponsor or manufacturer of an eligible investigational drug to notify the Food and Drug Administration of the provision of such a drug to an eligible patient within seven business days. In contrast, S. 204 only requires that the sponsor or manufacturer of an eligible investigational drug submit an annual summary of any uses of such drugs under the Right-to-Try pathway.

- H.R. 5247 would require physicians who receive an eligible investigational drug for use by an eligible patient under the Right-to-Try pathway to immediately report to the sponsor or manufacturer any serious adverse events associated with the use of the drug by the patient. No such reporting would be required by S. 204.

Thus, we strongly urge you to reject S. 204 because it would pose far greater danger to the health and welfare of patients than would H.R. 5247. And to better protect patients seeking access to investigational drugs, we encourage you to make amendments to H.R. 5247, as we recommended in our March 12, 2018, letter to you.[1]

Thank you for considering our views on this important matter.

Sincerely,

Michael A. Carome, M.D.
Director
Public Citizen's Health Research Group

[1] https://www.citizen.org/sites/default/files/2406.pdf.