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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

February 12th, 2018

Dear Speaker Ryan & Leader Pelosi,

The American Society for Pharmacology & Experimental Therapeutics (ASPET) strongly opposes H.R. 878, the *Right to Try Act of 2017*, and urges House leadership and all Members to reject this harmful legislation.

ASPET is a 5,000 member scientific society whose members conduct essential basic and clinical pharmacological research and work for academia, government, large pharmaceutical companies, small biotech companies, and non-profit organizations. ASPET members work in a variety of different fields and their efforts help to develop new medicines and therapeutic agents to fight existing and emerging diseases.

H.R. 878's proposal to grant terminally ill patients unrestricted access to experimental medications runs the risk of eroding patient safety and damaging the legitimate development of new efficacious treatments. The Right to Try legislation eliminates the Food & Drug Administration's (FDA) role in evaluating a patient's request, which means: there is no independent assessment of whether an approved treatment for a patient's condition exists, there is no weighing of benefits for the patient, and there is no review of the route of administration or dosage. Without proper safety tests and oversight, unintended effects such as enhanced pain to the patient or the acceleration of an individual's death are possible. Moreover, it could erode public faith in the drug development process.

ASPET also believes that the existing regulatory framework for accessing investigational therapies via the Food & Drug Administration's (FDA) "Compassionate Use" program is a sufficient and safer alternative to H.R. 878. The FDA already grants >99% of all expanded access requests from physicians and companies on behalf of patients with terminal illnesses. In the very small number of cases where the request has been denied, it has been for reasons that include: there is already an existing approved drug for the patient's condition that the patient has not tried, or there is an existing clinical trial for which the patient is eligible. When the FDA thinks the risks of a drug are significant or the uncertainties are very high, they have helped companies to design open label, single-arm clinical trials for patients seeking expanded access. Patients can then access the

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experimental medication and undergo extensive safety monitoring, and data can be collected.

There are ample opportunities to improve the “Compassionate Use” program and make access to experimental medications quicker and safer. However, legislation that purports to eliminate the FDA’s role entirely in getting investigational therapies to terminally ill patients runs the risk of needlessly and seriously harming patients. ASPET welcomes the opportunity to work with House leadership to streamline the current regulatory process while prioritizing patient safety and outcomes.

Sincerely,

A handwritten signature in black ink, appearing to read "John D. Schuetz". The signature is fluid and cursive, with a large, stylized initial "J" and "S".

John D. Schuetz, PhD
President, ASPET