

May 26, 2022

Chair Patty Murray  
Senate HELP Committee  
428 Senate Dirksen Office Building  
Washington, D.C. 20515

Ranking Member Richard Burr  
Senate HELP Committee  
428 Senate Dirksen Office Building  
Washington, D.C. 20515

Chairman Frank Pallone, Jr.  
House Committee on Energy & Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20510

Ranking Member Cathy McMorris Rodgers  
House Committee on Energy & Commerce  
2125 Rayburn House Office Building  
Washington, D.C. 20510

Dear Chair Murray, Ranking Member Burr, Chairman Pallone, and Ranking Member McMorris Rodgers:

On behalf of the undersigned organizations, representing a diverse group of patients, health care specialists, and taxpayer organizations, we write in strong support of S.1644/H.R. 3761, *the Promising Pathway Act*. This bipartisan legislation establishes a safe and effective approval process at the Food and Drug Administration (FDA) for therapeutic treatments that could treat, prevent, or diagnose life-threatening conditions including ALS, muscular dystrophy, and other rare diseases. As your committees consider legislation to reauthorize user fee agreements at the FDA and make other health care reforms in the coming weeks, we urge you to include the *Promising Pathway Act* to provide hope for your constituents that are suffering from rapidly progressing terminal illnesses.

While our organizations often have very different views on health care policy, we have united to support the *Promising Pathway Act* because it modernizes the FDA approval process by establishing a rolling, real-time, priority review pathway for promising drugs and biologics that could benefit countless patients. The legislation allows the FDA to grant provisional approval to drugs demonstrating substantial evidence of safety and relevant early clinical evidence of efficacy. Patients, in consultation with their doctors, would have access to approved therapeutics and real-world data from these patients would be incorporated into the FDA's broader approval system, strengthening our health care system. Importantly, supporting faster access to safe and effective therapies requires bolstering post-market surveillance requirements for drug sponsors, which is strengthened under this legislation. The *Promising Pathway Act* will increase innovation in clinical trial design and encourage pharmaceutical companies to use real-world data and flexible endpoints to determine the benefits of the drug without reducing the FDA's standard of safety or effectiveness.

First drafted in 2019, the PPA has received extensive input from stakeholders, including patient groups, pharmaceutical companies, and taxpayer groups, and has been thoughtfully revised to strike an appropriate balance between access to innovative treatments and patient safety. The legislation has gained bipartisan support because it prioritizes patients that are suffering while maintaining necessary safeguard that many, including members of Congress, value.

For these reasons, we strongly support S.1644/H.R. 3761, the *Promising Pathways Act*, and urge you to enact it as soon as possible. Patients that are suffering cannot afford to wait any longer for treatments that could change their lives for the better.

Sincerely,

Tarren Bragdon  
President and Chief Executive Officer  
Foundation for Government Accountability

Brent Wm. Gardner  
Chief Government Affairs Officer  
Americans for Prosperity

Laura McLinn  
Founding President  
Best Day Ever Foundation

Janet Demeter  
President  
Jack's Angels Inc  
DIPG Advocacy Group

Adam Brandon  
President  
FreedomWorks

Jessica Anderson  
Executive Director  
Heritage Action for America

Wendy Faust  
Executive Director  
LiveLikeLou Foundation

Valerie Estess  
Co-Founder & Director of Research  
Project ALS

David Williams  
President  
Taxpayers Protection Alliance

Keith Desserich  
Chairman, Co-Founder  
The Cure Starts Now International Foundation  
The DIPG/DMG Collaborative

Keith Desserich  
President  
The Pediatric Brain Tumor Consortium Foundation

Al Musella, DPM  
President  
Musella Foundation For Brain Tumor Research & Information, Inc

CC:

Senate Majority Leader Charles Schumer  
Senate Republican Leader Mitch McConnell  
Members of Senate Committee on Health, Education, Labor and Pensions (HELP)  
Members of the House Committee on Energy & Commerce