September 20, 2022

The Honorable Frank Pallone
Chairman
Committee on Energy & Commerce
House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Patty Murray
Chairwoman
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

The Honorable Cathy McMorris Rodgers
Ranking Member
Committee on Energy & Commerce
House of Representatives
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Dirksen Senate Office Building
Washington, DC 20510

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

As leaders of national patient advocacy organizations representing the cancer, Alzheimer's, and rare disease communities, we write to urge you to use the *Prescription Drug User Fee Act (PDUFA)* reauthorization to enact reforms to strengthen the Accelerated Approval drug review pathway. This pathway is a critical regulatory tool which has yielded life-saving therapies to many of the communities we serve. We believe you have a clear opportunity to strengthen and protect this pathway to help the U.S. Food and Drug Administration (FDA) continue to provide safe, effective, innovative therapies to millions of Americans living with serious and life-threatening conditions.

Since Accelerated Approval was first codified in 1992, the FDA has used it to bring nearly 300 drug indications to market. Of those, half demonstrated clear clinical benefit in post approval trials and eventually received traditional FDA approval. Only about 10 percent of all approvals were withdrawn. The other 100+ drugs remain eligible for consideration for traditional approval. While there are opportunities to enhance Accelerated Approval, the numbers clearly speak for themselves: this pathway successfully brings much-needed therapies to patients with devastating and rapidly progressing diseases.

We believe that both of your committees understand the value of Accelerated Approval and what is needed to strengthen the pathway going forward. Although there are some differences between the Accelerated Approval provisions in the *Food and Drug Amendments of 2022 (H.R. 7667)* and the *Food and Drug Administration Safety and Landmark Advancements Act of 2022 (S. 4348)*, there is much alignment. As you work together reach an agreed-upon approach to reauthorizing *PDUFA*, we hope you will not lose sight of the chance to strengthen this tool for bringing highly innovative therapies to the millions of patients who urgently need them.

Thank you for considering our input and if we can be helpful in your deliberations, please do not hesitate to contact us.

Sincerely,

Mark Dant
Chairman, Board of Directors
EveryLife Foundation for Rare Diseases

Andrea Ferris
President and CEO
LUNGevity Foundation

Melanie Lendnal
Senior Vice President
The ALS Association

Sue Peschin, MHS
President and CEO
Alliance for Aging Research

Ellen V. Sigal, PhD
Chair & Founder
Friends of Cancer Research

George Vradenburg
Co-Founder and Chair
UsAgainstAlzheimer's

Debbie Weir
CEO
Cancer Support Community

Cc: The Honorable Nancy Pelosi, Speaker of the House of Representatives
The Honorable Charles Schumer, Majority Leader, United States Senate
The Honorable Kevin McCarthy, Minority Leader, House of Representatives
The Honorable Mitch McConnell, Minority Leader, United States Senate