



March 16, 2022

The Honorable Frank Pallone
U.S. House of Representatives
237 Cannon House Office Building
Washington, DC 20515

The Honorable Cathy McMorris Rodgers
U.S. House of Representatives
1035 Longworth House Office Building
Washington, DC 20515

Dear Chairman Pallone and Ranking Member McMorris Rodgers,

We write today to convey our strong support for FDA's Accelerated Approval pathway and to convey to Congress the importance of preserving and strengthening this critical tool for bringing therapies to patients currently living with unmet medical need. At each turn when Congress has legislated on accelerated approval the pathway has been reaffirmed and the Agency has been encouraged to fully harness the promise of the pathway on behalf of patients. Lives have been saved, extended and improved.

Millions of American families are grateful for these past actions by Congress and fully expect this Congress to continue to support and encourage the use of accelerated approval for all of the patients who today live with unmet medical needs. Who are these patients? They are Americans living with rare diseases, 95% of which currently have no approved treatments. They are Americans living with conditions like Alzheimer's where treatments are just beginning to emerge but the unmet need remains vast or diabetes where treatments have emerged but there are still unmet needs in disease modifying therapies to address the underlying autoimmunity in type 1 diabetes. They are Americans, many of whom are children, whose disease progression means that the loss of certain core functions and mobility cannot be recovered if novel therapies take too long to clear the regulatory process. They are Americans for whom a curative treatment is on the horizon through game changing cell and gene therapies. And the list goes on.

As you begin consideration of the FDA User Fee reauthorization the undersigned organizations and our broader community of patients and families wants to be clear about our unequivocal support for preserving the accelerated approval pathway and ensuring that all patients living with unmet need, regardless of their specific condition, can continue to have confidence in the FDA's utilization of the pathway.

We stand ready to support any effort you may undertake to reaffirm Congress' ongoing support for accelerated approval. Just as we stand ready to support those efforts, we also stand ready to defend the pathway against any efforts that would intentionally or unintentionally limit FDA's ability to utilize the pathway or any efforts that would essentially undermine the use of or confidence in the pathway. HIV went from a death sentence to a chronic disease because of accelerated approval. Many cancers have been beaten back due to accelerated approval. It is

only reasonable to continue to offer that same hope and deliver on the same results for the millions of patients still living with unmet need.

Sincerely,

Robert Egge
Chief Public Policy Officer, Alzheimer's Association
Executive Vice President, Alzheimer's Impact Movement

Cynthia Rice
Chief Mission Strategy Officer, JDRF

CC:

Rep. Bobby Rush
Rep. Anna Eshoo
Rep. Diana DeGette
Rep. Michael Doyle
Rep. Janice Schakowsky
Rep. G.K. Butterfield
Rep. Doris Matsui
Rep. Kathy Castor
Rep. John Sarbanes
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