December 14, 2021

The Honorable Charles E. Schumer  
Majority Leader  
U.S. Senate  
322 Hart Senate Office Building  
Washington, DC 20510

The Honorable Ron Wyden  
Chairman, Committee on Finance  
U.S. Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Bernie Sanders  
Chairman, Committee on the Budget  
U.S. Senate  
624 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Mitch McConnell  
Minority Leader  
U.S. Senate  
317 Russell Senate Office Building  
Washington, DC 20510

The Honorable Mike Crapo  
Ranking Member, Committee on Finance  
U.S. Senate  
219 Dirksen Senate Office Building  
Washington, DC 20510

The Honorable Lindsey Graham  
Ranking Member, Committee on the Budget  
U.S. Senate  
624 Dirksen Senate Office Building  
Washington, DC 20510

Re: Importance of Orphan Drug Tax Credit for People and Families Living with Autoimmune Disease

On behalf of the estimated 50 million Americans with autoimmune and immune-mediated diseases, the undersigned 64 organizations write to you regarding the importance of the Orphan Drug Tax Credit (ODTC) for people and families living with autoimmune disease and urge you to protect the ODTC in the Build Back Better legislation.

Autoimmune and immune-mediated diseases are lifetime afflictions - there are currently no cures and they are among the leading causes of disability in this country. Individuals and families living with these diseases depend on many of the medicines that have come to market since the enactment of the 1983 Orphan Drug Act, and the millions living with a rare autoimmune disease who lack an FDA approved medication are depending on the Orphan Drug Tax Credit as a vital tool for future treatment development.

Since it was enacted the Orphan Drug Act has spurred the approval of 652 drugs for 1,006 rare diseases1. It has been a lifeline for millions of individuals with autoimmune diseases who face significant health challenges and often require a unique combination of drugs to

https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm
diagnose, treat, and manage their symptoms. In the current draft of ODTC in the Build Back Better legislation, only the first approved orphan use of a drug would be available for the tax credit. This limitation would unnecessarily curb critical incentives for companies to invest in orphan drug development, which are vital given over 90% of rare diseases have no FDA approved treatment².

The U.S. orphan drug development process is particularly significant for individuals living with rare autoimmune diseases as secondary indications have proven to be indispensable in the development of treatment for these individuals. Since 2016, 23 secondary orphan drug indications have been FDA approved for rare autoimmune diseases³. At such a promising time, Congress should be protecting and investing in the future of those without a current FDA approved treatment, rather than removing incentives for the development of future therapies for those who depend on it the most.

The Autoimmune Association and the undersigned organizations deeply appreciate the hard work you have undertaken to address issues of drug affordability for patients. Let’s continue to work together to find solutions and secure tomorrow’s cures today by investing in the promising pipeline that has already delivered so many vital drugs to patients living with autoimmune disease.

Please contact Brett McReynolds, Autoimmune Association, VP of Policy at brett@autoimmune.org. We look forward to continuing to work together to advance patient-centered policies that address affordability and access.

Sincerely,

ACCSES
Acromegaly Community, Inc
Advocacy & Awareness for Immune Disorders Association (AAIDA)
Advocates for Responsible Care
Alliance for Aging Research
Alpha-1 Foundation
American Academy of Allergy, Asthma, & Immunology
American Behcet’s Disease Association (ABDA)
American Liver Foundation

American Partnership for Eosinophilic Disorders
APS Foundation of America, Inc
Arizona United Rheumatology Alliance
Arthritis Foundation
Autoimmune Association
Brain Injury Association of America
California Chronic Care Coalition
Caregiver Action Network
Caring Ambassadors Program
Chronic Care Policy Alliance
Chronic Disease Coalition
Color of Crohn’s and Chronic Illness

³ Based off data from Biomedtracker