

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

¹ FDA. Orphan Drug Database. Accessed 9/13/21.
<https://www.accessdata.fda.gov/scripts/opdlisting/oopd/index.cfm>

diagnose, treat, and manage their symptoms. In the current draft of ODT 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 Coaliton
Caregiver Action Network
Caring Ambassadors Program
Chronic Care Policy Alliance
Chronic Disease Coalition
Color of Crohn's and Chronic Illness

² "Rare Diseases." *National Institutes of Health*, <https://www.nih.gov/about-nih/what-we-do/nih-turning-discovery-into-health/rare-diseases>

³ Based off data from Biomedtracker

Conquer Myasthenia Gravis
CURED Nfp
Cystic Fibrosis Research Institute
DCAN
Fabry Support & Information Group
Foundation for Sarcoidosis Research (FSR)
Gaucher Community Alliance
GBS|CIDP Foundation International
Global Healthy Living Foundation
Global Liver Institute
ICAN, International Cancer Advocacy
Network
Immune Deficiency Foundation
International Foundation for Autoimmune
& Autoinflammatory Arthritis (AiArthritis)
International Pain Foundation
International Pemphigus Pemphigoid
foundation
Jeffrey Modell Foundation
Lupus and Allied Diseases Association, Inc.
MANA, A National Latina Organization
Men's Health Network
Mississippi Arthritis and Rheumatism
Society

MLD Foundation
Myasthenia Gravis Foundation of America
National Alopecia Areata Foundation
Neuropathy Action Foundation
Nevada Chronic Care Collaborative
Patient Advocacy Strategies
Patients Rising Now
Prevent Blindness
Project Sleep
Pulmonary Hypertension Association
Relapsing Polychondritis Foundation
RetireSafe
Rheumatology Nurses Society
Scleroderma Foundation
Sjogren's Foundation
Solve ME/CFS Initiative
SYNGAP1 Foundation
Texas Rheumatology Care
The National Adrenal Diseases Foundation
(NADF)
The Sumaira Foundation
US Hereditary Angiodema Association
Vasculitis Foundation
Wisconsin Rheumatology Association