

The Honorable Rosa DeLauro
Chair
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Patrick Leahy
Chair
Committee on Appropriations
U.S. Senate
Washington, DC 20510

The Honorable Kay Granger
Ranking Member
Committee on Appropriations
U.S. House of Representatives
Washington, DC 20515

The Honorable Richard Shelby
Vice Chair
Committee on Appropriations
U.S. Senate
Washington, DC 20510

Dear Chairwoman DeLauro, Chairman Leahy, Ranking Member Granger, and Vice Chairman Shelby:

On behalf of over 36 organizations focused on autoimmune diseases and the millions in the US suffering from them, we urge Congress to swiftly complete the FY 2023 omnibus funding bill incorporating the House approved \$47.5 billion appropriation that includes the recommendation to establish an Office of Autoimmunity within the Director's Office of the National Institutes of Health.

Our concern is that by merely extending the current continuing resolution (CR) beyond December 16th, without language authorizing the establishment of an Office of Autoimmunity within the Director's Office of the National Institutes of Health, progress on dealing with autoimmune diseases will continue to be impeded due to the lack of a comprehensive, coordinated and focused approach to autoimmune research that is needed to address this neglected and looming crisis effectively.

Autoimmune and immune-mediated conditions are fast reaching epidemic proportions. These conditions are chronic and debilitating conditions that very often afflict patients for years before they are diagnosed if they ever are. Many of these conditions have limited treatment options, and many patients face difficulty obtaining treatment due to limited access and high cost. While the National Institute of Environmental Health Sciences (NIEHS) reports that 23 million to 31.5 million U.S. residents suffer from an autoimmune disease, that number incorporates only 29 autoimmune diseases based on ten-year-old data. Our organizations are aware of 180 autoimmune diseases. The current lack of a central registry of incidences of these diseases or even regional registries, as there is for cancer, is a fundamental obstacle to effective research which the establishment of an Office of Autoimmunity within the Director's Office of the National Institutes of Health would do much to overcome.

In 2020, the Autoimmune Association internal report pulled all the incidence and prevalence data from the NIEHS for 111 autoimmune conditions, and the result was approximately 80 million people. We have spoken with many researchers who support that total number. Additionally, recent research on antinuclear antibodies, commonly used biomarkers to test for autoimmunity, indicates that these biomarkers are also on the rise. Of particular concern is the nearly three-fold increase seen in just over 20 years among children ages 12-18, many of whom can be expected to develop a chronic, incurable illness at some point in their lives.

While there are many impediments to developing a comprehensive national plan to address this crisis, three primary obstacles prohibit rapid progress. 1) The lack of consensus on what the essential attributes of an autoimmune disease are or even agreement on which specific illnesses constitute an autoimmune disease, which impedes research and clinical care 2) The extrapolation of incidence of

autoimmune diseases based on countries, primarily Scandinavian, which maintain registries of the incidence and treatment of autoimmune diseases. Statistics from these countries cannot possibly reflect the diversity of the US population or the environmental conditions in the US that researchers state probably play a role in increasing the overall incidence and prevalence of autoimmune diseases. The US simply does not have a central registry or mandated reporting systems (similar to SEER for cancer) that will allow us to assess trends, and clearly identify the prevalence and incidence of under-researched autoimmune diseases and conditions; 3) any focused strategy to research autoimmune diseases. The NIH is the primary agency for autoimmune research in the U.S.; twelve of the 24 Institutes and Centers (ICs) undertake the majority of publicly funded research, including what research there currently is into autoimmune diseases. Each IC, however, has different metrics, reporting standards, and methods that need to be more centrally coordinated regarding autoimmune diseases.

There is also the looming crisis of the overall cost to society. Because of the fragmentation of our healthcare system, the total direct and indirect costs of autoimmune diseases are difficult to assess. They are, however, a significant driver of healthcare utilization, with direct costs estimated at \$100 billion (considered by many to be a gross underestimate) and potentially upwards of \$500 billion – or 2/3 of what is spent on Medicaid.

Earlier this year, the Congressionally mandated report by The National Academies of Sciences, Engineering, and Medicine (NASEM) contained a primary recommendation that an Office of Autoimmunity under the NIH Director's Office with a mandate to increase research and clinical efforts, resources, and coordination be established to enable dealing with autoimmune diseases on a scale not undertaken previously. The office would:

- Establish strategic research planning to set priorities.
- Coordinate efforts across ICs and promote collaborative research;
- Evaluate the autoimmune research portfolio to determine progress made across NIH, as well as other agencies;
- Focus on new, promising, innovative research methods;
- Establish long-term systems to collect and ensure optimum usability of population-based surveillance and epidemiological data;
- Ensure the resources are available to support planning, collaboration, and innovation.

Without intervention and change, the incidence of autoimmune diseases will continue to rise and have an increasingly devastating impact on more people and society. It is imperative that we adopt a coordinated, focused approach to decrease the future frequency, morbidity, mortality, and costs of these conditions and protect our children from a future of chronic illness.

For these reasons, we urge you to move swiftly to pass a final appropriations bill that includes report language, including the NASEM recommendation that NIH establishes an office to support the coordination of all autoimmune disease research across Institutes and Centers.

Should you have any questions, or if you would like additional information about the work of NASEM, please get in touch with Quardricos Driskell at quardricos@autoimmune.org who will be happy to assist or provide you with a contact at any of the organizations below.

Sincerely,

Advocacy & Awareness for Immune Disorders Association (AAIDA)
Alliance for Patient Access
American Bechet's Disease Association (ABDA)
Autoimmune Association
Beyond Celiac
California Chronic Care Coalition
Celiac Disease Foundation
Children with Diabetes
Chronic Care Policy Alliance
Coalition of Skin Diseases
Color of Crohn's and Chronic Illness
Crohn's & Colitis Foundation
CURED Nfp
Diabetes Leadership Council
Diabetes Patient Advocacy Coalition
Dysautonomia International
Foundation for Sarcoidosis Research
Global Liver Institute
Immune Deficiency Foundation
International Foundation for Autoimmune & Autoinflammatory Arthritis
International Pemphigus Pemphigoid Foundation
Lupus and Allied Diseases Association, Inc.
Lupus Foundation of America
LupusChat
Men's Health Network
National Alopecia Areata Foundation
National Scleroderma Foundation
Nevada Chronic Care Collaborative
Platelet Disorder Support Association
RetireSafe
Sjogren's Foundation
Solve M.E.
Texas Rheumatology Care
The Lambert-Eaton LEMS Family Association
Triage Cancer
Virginia Breast Cancer Foundation
WAIHA Warriors

Cc:

The Honorable Nancy Pelosi, Speaker, U.S. House of Representatives
The Honorable Kevin McCarthy, Minority Leader, U.S. House of Representatives
The Honorable Charles Schumer, Majority Leader, U.S. Senate
The Honorable Mitch McConnell, Minority Leader, U.S. Senate
