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April 7, 2025

The Honorable Chip Roy
103 Cannon House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Morgan Griffith
2110 Rayburn House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Harriet Hageman
1227 Longworth House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Elijah Crane
307 Cannon House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Josh Brecheen
351 Cannon House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Andy Harris
1536 Longworth House Ofc. Bldg.
Washington, D.C. 20515

The Honorable Paul Gosar
2057 Rayburn House Ofc. Bldg.
Washington, D.C. 20515

RE: H.R. 1497, the *NIH Reform Act*

Dear Representatives Roy, Griffith, Hageman, Crane, Brecheen, Harris, and Gosar:

Established in 1943, the American Academy of Allergy, Asthma & Immunology (AAAAI) is a professional organization with more than 6,700 United States members. We are subspecialist internists and pediatricians who practice allergy and immunology and take care of adults and children with life threatening illnesses such as food allergy, asthma and severe combined immune deficiency. Our lifesaving work improves the lives of millions of our US citizens and depends profoundly on transformative treatments that come from federally funded scientific and clinical research by the National Institutes of Health. Importantly our work would not be possible without the National Institute of Allergy and Infectious Diseases (NIAID) and we see the integration of allergy, Infectious disease and immunology as central to innovation for our patients.

Thus, we write to convey our serious concerns with your proposal to abolish the NIAID and replace it with the three separate research institutes: the National Institute of Allergic Diseases, National Institute of Infectious Diseases, and National Institute of Immunologic Diseases. As America's Allergists/Immunologists this move would split our specialty and reduce the collaborative thinking that cures and prevents disease.

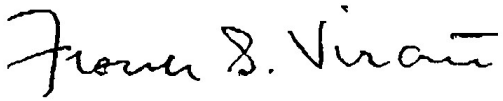
It would also create new administrative hurdles to create and cultivate new concepts across three institutes at a time when the national focus is on efficiency.
The NIAID leads cross-cutting and cross-disciplinary research that importantly has addressed many of the greatest needs of our time. These include the successful treatments for AIDS and the prevention of its transmission, prevention of asthma in youth in our cities, and prevention of fatal food allergy through blocking allergic antibody (Immunoglobulin E) as well as the development of curative oral food allergen desensitization regimens. Attached are examples of NIAID support which focus on better understanding allergic and immunologic disease to open up opportunities for prevention and new forms of treatment.

We strongly believe that the disciplines of allergic diseases and immunology should not be separated from infectious diseases. Infectious disease (ID) research, allergy research and immunology research are fundamentally intertwined as all three fields are linked by how the human immune system keeps us healthy and how it responds to and protects against microbes. For example, ID research may focus on how bacteria or viruses invade, replicate, and mutate to make us sick; while allergy helps us understand how our immune system may become confused and inappropriately respond to a food or mold, and immunology research investigates how the immune system identifies and controls pathogens (bacteria, fungi, viruses), allergens (allergic disease) and our own body tissues (autoimmunity). These interactions are central to successful research and have generated treatments and strategies for disease prevention.

Studying interactions between microbes contributing to allergic inflammation and autoimmunity has been a cornerstone of NIAID research and has led to a host of new medications effective in treating these disorders. Recent years have seen an emerging understanding of the variability of the microbiome (bacteria, fungi, and viruses residing in various organs [e.g., lungs, skin, GI tract] in our bodies) as a determinant for the development of or protection from allergic disease. We are concerned that separating these key areas of research is counter to the very inter-connected nature within the immune system including allergic inflammation, autoimmunity and infections. Further, we are concerned that separating these fundamentally intertwined disciplines results in less efficiency in moving these strongly linked scientific fields forward to continue the impressive therapeutic gains in better management and prevention of so many disorders and conditions.

On behalf of Allergists/Immunologists across America, we urge you to reconsider your proposal, and we express our strong support for maintaining the current structure of NIAID. We appreciate your consideration of our concerns, and we stand ready to serve as a resource to you. Should you have any questions, please contact Sheila Heitzig, Director of Practice and Policy, at sheitzig@aaaai.org or (414) 272-6071.

Sincerely,



Frank S. Virant, MD FAAAAI
President, American Academy of Allergy, Asthma & Immunology

NIAID Support of Allergic and Immunologic Disease Research

- Funded the **Immune Tolerance Network (ITN)** for more than two decades and this international collaborative effort to control inflammatory responses causing human disease has supported 18 allergy trials, 32 autoimmunity trials and 25 transplantation trials. A recent example of a major impact of ITN clinical trials in allergic disease is the **LEAP study demonstrating that peanut allergy can be effectively prevented in many infants by early introduction of peanut** into the diet (New England Journal of Medicine 2015) and this continues to provide valuable information from long term follow up data.

- Funded the **Consortium for Food Allergy Research (CoFAR)** since 2005. **Food allergy (FA) is very common, affecting up to 32 million Americans, including up to 8% of children and 10% of adults**, and its prevalence appears to have increased significantly over the past 20 to 25 years. The past two decades, under CoFAR has yielded significant advances in prevention and treatment, as well as in the understanding the immunologic basis of FA:
    - **Identifying the mechanisms underlying the development of new food allergy and the mechanisms of outgrowing food allergy** (i.e., emergence of oral tolerance to food allergens). These studies have had a major impact on the lives of Americans by proving that early peanut introduction prevents lifetime peanut allergy;
    - **Supported development of immune intervention strategies for the treatment of food allergy**, including oral, sublingual, and epicutaneous immunotherapy;
    - Conducted a Phase 3 trial **of omalizumab for the treatment of patients with FA**, leading to an FDA approval of the first treatment for patients with multiple FA;
    - Developing biomarkers to improve and simplify the diagnosis of FA;
    - Identifying the genes and the epigenetic alterations associated with FA;
    - Establishment of a new birth cohort study **that is specifically focused on the immunologic, microbiologic, genetic, environmental factors that underlie FA**.

- Provided long-term support for **birth cohort studies in asthma, atopic dermatitis and food allergy** that have provided **new insights into risk factors for developing asthma and other allergic diseases**. **Childhood asthma** is an outstanding example of a disease with its **roots in both infectious disease and immune development** with studies demonstrating that viral and bacterial pathogens are the principal causes of early childhood wheezing illnesses and the #1 cause of hospitalization in young children. The **combination of infections and allergies cause most asthma attacks in children and adults** and treating allergic inflammation reduces virally induced childhood asthma. In addition, **exposures that interfere with normal immune development promote recurrent wheezing illnesses, chronic childhood asthma, and other allergic diseases**. Studying both infections and immune development has identified preventive approaches for the emergence of asthma. Additional major advances in understanding and caring for children with asthma from NIAID funded studies demonstrated:
    - The **efficacy of omalizumab in children with asthma** leading to FDA approval in children as young as 6 years. These studies also demonstrated that omalizumab improved response to viral infections leading to fewer severe asthma attacks;
    - The first **efficacy of mepolizumab in managing children with asthma** $\geq$ 6 years

- Provided long term support on the mechanisms causing **atopic dermatitis/eczema** via the **Atopic Disease Research Network** (**ADRN,** initiated in 2004) that have focused on: understanding the difference in host defense mechanisms to bacterial and viral infections

between healthy individuals and patients with AD and understanding the immune system of AD patients in order to generate new therapeutic targets:
    - This successful initiative led to the demonstration that **allergic inflammation together with defective skin barriers promote chronic staphylococcal infections that drive acute and chronic AD symptoms**. Another link to the **intersection between infectious and allergic inflammatory pathways**;
    - Successful therapy developed via this program include **recent FDA approval of biologics for difficult to manage moderate to severe atopic dermatitis using monoclonal antibodies (dupilumab and tralokinumab) and a JAK inhibitor**.

- Provided long term support on **disorders involving eosinophils (the hyper-eosinophilic syndrome [HES] and eosinophilic esophagitis [EOE])**. NIAID co-funded the **Consortium for Eosinophilic Gastrointestinal Researchers (CEGIR)**. These rare eosinophilic diseases impacting the gastrointestinal tract can cause severe symptoms including significant eating difficulties often due to food being unable to pass the esophagus. The consortium identified genes and cellular pathways responsible for symptoms that yielded medications for these disorders including the **recent approval of dupilumab in managing EOE**.

- Provided **support of research on disorders involving mast cells** including mastocytosis and mast cell activation syndrome (MAS). This work has resulted in recent FDA **approval of a new concept biologic (tyrosine kinase inhibitor) for the treatment of adult indolent systemic mastocytosis**.

- Long term funding to study **immune function involved in allergic diseases** set the stage for developing therapeutics targeting specific immunologic pathways via **new biologics in difficult to manage patients with allergic and immunologic diseases (e.g., targeting IL4/IL13, IL5, IL23, TSLP, IgE and using agents that inhibit the JAK-STAT pathways**).

- NIAID funded research has made major contributions to understanding the **microbiome that contributes to or protects from the development of allergic disease**. One novel area of investigation focuses on **modifying the skin microbiome towards a protective status for C-section delivered newborns** based on documentation that these babies have an increased risk for developing allergic diseases compared to vaginally delivered babies.

- Provided major support for research focused on **inborn errors of immunity (primary immunodeficiencies)** with many new disorders and therapies identified:
    - **JAK inhibitors for selected immune defects** and targeted **therapy in treating activated phosphoinositide 3-kinase syndrome**;
    - **Innovations in hematopoietic stem cell therapy (HSCT)** supported by the NIAID sponsored **Primary Immune Deficiency Treatment Consortium (PIDTC);**
    - Successful application of **gene therapy** for correction of specific immune defects
    - Identifying secondary **immunodeficiencies due to autoantibodies directed at immune mediators (cytokines)** treated by decreasing autoantibody levels.