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**STATEMENT OF THE
AMERICAN ACADEMY OF ALLERGY, ASTHMA
AND IMMUNOLOGY**

**TO THE
HOUSE COMMITTEE ON ENERGY AND COMMERCE**

TO THE

on the

21st Century Cures Initiative

June 13, 2014

The American Academy of Allergy, Asthma and Immunology (AAAAI) is a professional organization of more than 6,000 members. Our membership includes allergist/immunologists, other medical specialists, allied health and related health care professionals who focus on research and treatment of allergic and immunologic diseases. The AAAAI applauds the Committee's effort to examine ways to accelerate the pace of biomedical discoveries and to bridge the gap between the laboratory bench and the patient bedside. Following are the Academy's responses to a number of the questions raised in the Committee's May 16, 2014 request for comments.

What is the state of discovery of cures and treatments for your disease? Are there cures and treatments now or on the horizon?

Allergen Immunotherapy: Often referred to as "allergy shots," allergen immunotherapy (AIT) has the potential for curing allergic rhinitis and the allergic component of asthma. It involves a long-term treatment that decreases symptoms for many people with hay fever, allergic asthma, eye allergy, or stinging insect allergy. Unlike more expensive symptomatic treatment, AIT modifies the allergic disease. While traditionally involving regular injections, there has been significant progress in the development of sublingual immunotherapy in recent years. In April, the FDA approved the first sublingual tablets for the treatment of grass and ragweed allergy. Researchers are engaged in testing approaches to potentially groundbreaking immunotherapy for patients with food allergy as well. In short, this 100-year-old therapy is now the focus of very exciting, transformative developments.

Despite the known clinical effectiveness of AIT, studies have shown that it is severely underutilized. The Academy is pleased that the National Institute of Allergy and Infectious Diseases (NIAID) is working with the Agency for Healthcare Research and Quality to convene a workshop of experts on AIT in 2015. Progress toward improved treatment for asthma and allergic diseases can be made if the research recommended by such a panel is funded.

Food Allergy: In the area of food allergy, the only effective treatment is avoidance. The most promising research is in the area of immunotherapy, which has been shown to have a beneficial effect on the amount of the allergenic food that is tolerated without inducing severe reactions. Clinical trials are pursuing various strategies, including topical, oral and sublingual immunotherapy, as well as testing monoclonal antibodies as additional strategies to improve safety of immunotherapy for food allergy. Again, the NIAID has been the principal sponsor of research on food allergies. The NIAID has also developed clinical guidelines for the diagnosis and management of food allergies.

As recently as 2003, the NIH spent less than \$2 million on food allergy research. Today, over \$25 million is allocated. While this growth has been impressive, it is important to note that approximately 15 million Americans suffer from food allergies. It would be difficult to identify another disease affecting such a large population toward which NIH dedicates such a minute fraction of its budget. Limited funding is slowing progress toward a treatment for food allergies.

Asthma: Major advances have been made in identifying differences in asthma from patient to patient; differences that predict severity and morbidity; and methods to more effectively identify those at greatest risk for asthma attacks. An important focus is asthma in the African American and Hispanic populations, since asthma affects these groups disproportionately in terms of both frequency and severity. Basic research discoveries must be translated to determine which treatments will be most effective for those patients at greatest risk.

In October of 2013, the National Heart, Lung, and Blood Institute (NHLBI) held a workshop on the primary prevention of asthma. The report of that workshop recommends basic and clinical research to test asthma prevention strategies. Funding for such initiatives could result in significant reduction in the prevalence and high cost of asthma.

The NHLBI has published guidelines for the diagnosis and management of asthma. Efforts to reduce asthma exacerbations and death depend on research to develop methods of improving physician and patient adherence to these guidelines.

Drug Allergy: Allergic reactions to medications are a serious medical problem. Inability to tolerate antibiotics and aspirin complicate care for routine medical problems. In addition, patients experience allergic reactions to drugs for debilitating and potentially fatal diseases including cancer, HIV/AIDS, cystic fibrosis, and rheumatoid arthritis. In early 2013, the NIAID sponsored a workshop to develop a research agenda on the diagnosis and management of patients with drug hypersensitivity. Minimal NIH funding is dedicated to this problem. Progress will not be made unless an initiative to implement the research recommendations of the 2013 workshop is developed and funded.

Eosinophil-Related Disorders: Eosinophilic disorders occur when eosinophils, a type of white blood cell, are found in above-normal levels in various parts of the body and trigger chronic inflammation that can result in tissue or organ damage. In some cases, this results from an allergy-triggering food or airborne allergen. There are no effective treatments for these diseases. For many patients with eosinophilic gastrointestinal disorders, it is impossible to eat normal foods, forcing a reliance on elemental formula or GI tube feeding. Under the leadership of the NIAID, the NIH convened the Task

Force on the Research Needs of Eosinophil-Associated Diseases (TREAD). Members of the House and Senate Appropriations Committee have strongly encouraged the NIH to implement a multi-Institute, multi-disciplinary research initiative on eosinophil-related disorders. Progress in this area depends on funding for this effort.

Immunologic Diseases: Primary Immune Deficiency Diseases (PIDDs) affect approximately 500,000 people in the United States. Such diseases are associated with significant morbidity and mortality, especially in early childhood. The development of targeted immune-based therapies has been shown to favorably treat and alter the progression of some PIDDs. Transplantation is another approach that has demonstrated success. However, these therapies are associated with adverse effects. New, more focused therapeutic strategies are in development. Additional research is needed to better understand and refine these and other approaches to the care of PIDDs.

What programs or policies have you utilized to support and foster research, such as patient registries, public-private partnerships, and venture philanthropy?

Since it was founded by the Academy in 1993, the Allergy, Asthma, and Immunology Education and Research Trust has provided almost \$5 million to support 80 junior and established investigators in our field. The Academy interacts closely with Food Allergy Research and Education; the American Partnership for Eosinophilic Disorders; the American Lung Association; and other patient groups dedicated to serving patients and funding research. The Centers for Medicare and Medicaid Services (CMS) has approved the AAAAI Allergy, Asthma & Immunology Quality Clinical Data Registry as a Qualified Clinical Data Registry (QCDR). The focus is quality measures for allergy immunotherapy and asthma. Data from the registry can be used to analyze approaches to improving the quality of care for these conditions.

What is the role of government in your work, including any barriers to achieving your goals and advancing breakthroughs?

The major barriers to advancing breakthroughs in our field and others are: 1) the shrinking population of active physician scientists, particularly those focused on patient-oriented research; and 2) the difficulty of getting translational research funded by the NIH. In 2000, the Congress enacted the Clinical Research Enhancement Act to address these problems, but the programs authorized in that legislation are inadequate to the challenge of ensuring that the NIH rescues the clinical investigator from becoming an endangered species, as first described by NIH Director James

Wyngaarden over three decades ago. The Academy encourages the Committee to examine this issue as perhaps THE most important barrier to progress toward cures and new therapies. A major program should be implemented through which NIH funds the patient-oriented, bench-to-bedside-to-bench research that is necessary for medical innovation.

What is the financial burden of your disease? How would better treatments and cures help save money for your family and the federal government?

Asthma and allergic diseases affect 1 in 5 Americans. The annual cost of asthma is estimated at \$18 billion, and asthma is the fourth leading cause of work absenteeism. Among children age 5-17, asthma is the leading cause of missed days from school.

Allergic rhinitis (hay fever) is the fifth most costly chronic disease in the U.S, with total direct costs estimated at \$11.5 billion.

Food allergies account for an emergency room visit every three minutes in the United States. Food allergies affect about 8 percent of children in the United States at a cost of \$25 billion including medical care, family expenses, special diets and allergen-free foods.

For additional information on this statement, please contact Lynn Morrison at Lynn.Morrison@whaonline.org.