



OVERVIEW OF THE AMERICAN ACADEMY OF ALLERGY, ASTHMA & IMMUNOLOGY (AAAAI) AND THE AMERICAN COLLEGE OF ALLERGY, ASTHMA & IMMUNOLOGY (ACAAI)

The American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma & Immunology (ACAAI) are professional organizations representing allergist/immunologists across the United States, Canada, and 72 other countries. Our members include board certified allergist/immunologists, other medical specialists, allied health and related healthcare professionals – all with a special interest in the research and treatment of patients with allergic and immunological diseases. These organizations represent a diverse group of professionals focused on advancing the knowledge and practice of allergy, asthma and immunology for optimal patient care.

A board certified allergist/immunologist (commonly referred to as an allergist) is a physician specially trained to diagnose, treat and manage allergies, asthma and immunologic disorders, including primary immunodeficiency disorders. These conditions range from the very common to the very rare, spanning all ages and encompassing various organ systems. The American Board of Allergy and Immunology (ABAI) establishes qualifications and examines physicians to become recognized specialists in allergy and immunology. The ABAI is a conjoint board of the American Board of Internal Medicine and the American Board of Pediatrics.

For additional information or if you have any questions, please contact Sheila C. Heitzig, JD, MNM CAE, AAAAI's Director of Practice & Policy at 414-272-6071 or sheitzig@aaaai.org.



ENSURE ADEQUATE NIH AND AHRQ FUNDING

REQUEST

The American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) ask that you ensure adequate federal research funding for the National Institutes of Health (NIH) and the Agency for Healthcare Research and Quality (AHRQ). **For NIH, AAAAI requests an increase of at least \$2 billion above fiscal year (FY) 2017 appropriations to account for inflation. For AHRQ, AAAAI urges you to restore the agency's funding to at least \$364 million in FY'18.**

SUMMARY

As part of the FY'17 omnibus appropriations bill (April 2017), Congress provided an additional \$2 billion for NIH in FY'17. President Trump's FY'18 budget request released on March 13, 2017 included a \$5.8 billion reduction in NIH funding (to a FY'18 amount of \$25.9 billion), as well as consolidating the work of AHRQ within NIH with no additional funding (reducing the effective NIH research budget to \$25.6 billion).

BACKGROUND

Each year, billions of dollars are spent treating the causes and symptoms of food, drug and skin allergy, immunodeficiency, and asthma. Multiple studies have found that NIH investments in research focused on a particular area stimulate increased private investment in the same area. A \$1.00 increase in public basic research stimulates an additional \$8.38 of industry R&D investment after 8 years. A \$1.00 increase in public clinical research stimulates an additional \$2.35 of industry R&D investment after 3 years. Through NIH supported research, we have the opportunity to identify and develop life-saving and life-improving treatments for these widespread chronic conditions. This past October, National Institute of Allergy and Infectious Diseases (NIAID) supported researchers announced promising results from an NIH sponsored clinical trial on the efficacy and value of an intervention for treating children and young adults with peanut allergies. This January, a NIAID-sponsored expert panel issued clinical guidelines to help healthcare providers educate parents and caregivers on the benefit of early introduction of peanut-containing foods to infants as a way to prevent development of peanut allergy. These impactful results are what the American people can expect from supporting the NIH and medical research.

We want to thank Congress for its recent increase in funding for the NIH as part of the omnibus appropriations bill. Adequate funding is necessary to continue the research initiatives underway and to allow for new grants. For example, NIAID issued a report from its Drug Allergy Workshop. Stable NIH funding will allow implementation of the report's recommendations regarding penicillin allergy testing and desensitization as a means to examine whether penicillin is appropriate for a patient before prescribing more expensive or newer antibiotics – a key tenet of antibiotic stewardship.

AHRQ is the only federal research agency with the sole purpose of producing evidence to make health care safer; of higher quality; more accessible, equitable, and affordable; and to ensure that the evidence is understood and used. AHRQ-funded research, tools, and datasets are being used in health settings across the nation to help us understand and improve a complex and costly health system so that better outcomes for more people at greater value can be achieved. AHRQ's research and data help Americans get their money's worth when it comes to health care. We need more of what AHRQ provides, not less.

We sincerely thank the 217 members of the House of Representatives who endorsed the request for at least \$36 billion in NIH funding for FY'18 in a bipartisan letter to the House Appropriations Committee. Also, we appreciate that 43 bipartisan members of the House of Representatives wrote the House Appropriations Committee to request \$364 million in FY'18 for AHRQ.



ENSURE PATIENT ACCESS TO ALLERGY SHOTS: IN-OFFICE DRUG COMPOUNDING

REQUEST

The American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) ask that you **ensure patients have continued access to allergen immunotherapy (AIT), also known as “allergy shots”**. Allergy/immunology (A/I) physicians prepare allergen extracts based on individual patient’s allergies, and have developed specific expertise in how to prepare these allergen extracts for their patients that is not shared by other pharmaceutical compounders. In fact, A/I physicians have been providing AIT for over 100 years, improving the quality of life for millions and saving the lives of those with potentially deadly anaphylactic reactions, such as to stinging insects. A/I physicians have been providing this treatment under safety standards established by the United States Pharmacopeia (USP) in 2007, and there is no data to show that this practice, as used to treat millions of patients over many years, has resulted in any serious infections. In addition, a 2013 report by the Agency for Healthcare Research and Quality¹ concluded that AIT is both safe and effective. AIT has long been known to prevent the development of new allergies and asthma; it also reduces overall healthcare costs.²

SUMMARY

The USP, a scientific nonprofit organization whose drug standards are enforceable in the United States by the US Food and Drug Administration (FDA), recently proposed to eliminate access to AIT by significantly revising its sterile compounding standards set forth in its General Chapter <797> Pharmaceutical Compounding for Sterile Preparations. These revisions are being proposed without evidence to substantiate that allergen extract compounding practices pose any harm or adverse impact to patients.

In August 2016, the FDA issued draft guidance -- “Insanitary Conditions at Compounding Facilities” -- that sets forth new standards (e.g., requiring physicians that compound drugs in their offices to have engineering control devices capable of maintaining an ISO Class 5 environment or be deemed “insanitary”) without scientific evidence to suggest this level of precaution is warranted. Moreover, the process under which these new standards are being established circumvent ongoing deliberations to update USP General Chapter <797>, which FDA currently recognizes as required under statute.

BACKGROUND

In response to a 2012 fungal meningitis outbreak, the Drug Quality and Security Act (Public Law 113-54) was adopted in November 2013, clarifying that the FDA has authority over compounding of human drugs. The FDA endorsed USP General Chapter <797> Pharmaceutical Compounding for Sterile Preparations as the standard to be followed for pharmaceutical compounding in most settings. Those guidelines currently provide a partial exemption from the personnel, environmental and storage requirements for allergen extract preparation that apply under General Chapter <797>, which includes most sterile compounding under the USP, so long as a separate chapter specifically addressing appropriate procedures were followed for immunotherapy mixing.

¹ <http://www.ncbi.nlm.nih.gov/books/NBK133240/>

² <https://www.ncbi.nlm.nih.gov/pubmed/25887973>



NETWORK ADEQUACY: PATIENT ACCESS TO ALLERGY, ASTHMA AND IMMUNOLOGY SPECIALISTS

REQUEST

The American Academy of Allergy, Asthma, and Immunology (AAAAI) and the American College of Allergy, Asthma, and Immunology (ACAAI) **urge Congress to ensure health plans adhere to uniform, reliable network adequacy standards to provide patients with timely access to the right care, in the right setting, by the most appropriate provider.**

SUMMARY

The Affordable Care Act (ACA) requires that Qualified Health Plans (QHPs) meet network adequacy standards. The Centers for Medicare and Medicaid Services (CMS) recently finalized regulations¹ that defer to States and accrediting bodies to establish and enforce standards related to network adequacy. This approach caused concern from stakeholders, as it overrode CMS' previous time-distance standards. CMS noted its intent to monitor how many States have adopted the National Association of Insurance Commissioners' (NAIC) Health Benefit Plan Network Access and Adequacy Model Act, which was updated in October 2015. In addition, CMS plans to monitor network adequacy through tracking complaints. For Medicare Advantage (MA) plans, CMS uses quantitative measurements of network adequacy, but there are documented concerns with access in MA plans as well.²

The updated NAIC Model requires stronger disclosures by plans concerning the development and operation of their networks, bolsters the authority of state insurance departments to decide whether a network is adequate, and sets more stringent rules designed to increase the accuracy of provider directories. However, to date, few states have updated their laws since the revised model law came out.

The issue of network adequacy is related to provider directories. Often, directories are outdated or inaccurate so that even consumers who do their research before seeking care may inadvertently end up with a provider who is out of network. Consumers may not have reliable information to support their decision-making when they choose a health plan or, once they choose a plan, when they choose a provider.

BACKGROUND

Network adequacy generally refers to a health plan's ability to provide reasonable access to a sufficient number of physicians and hospitals. Using this strategy, health plans including MA and Health Insurance Exchange plans only contract with physicians and hospitals that are deemed less expensive when compared to their local competitors. There is minimal regard for the severity of diseases treated or resulting health care quality. Narrow networks frequently exclude "expensive" physicians and hospitals, including many specialists that treat rare or complex health conditions. Health plans are quickly adopting narrow networks as a strategy to control costs and keep premiums artificially low to attract new and retain existing consumers. The non-uniform and vague nature of existing regulations allows insurers to freely narrow provider networks without concern for audit or enforcement by federal or state agencies. Moreover, the burden of proof of network inadequacy is placed solely on providers and at-risk patients.

¹ <https://www.federalregister.gov/documents/2017/04/18/2017-07712/patient-protection-and-affordable-care-act-market-stabilization>

² https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/MA_Network_Adequacy_Criteria_Guidance_Document_1-10-17.pdf



American
College
of Allergy, Asthma
& Immunology

April 11, 2017

The Honorable Tom Cole
Chair, House Appropriations
Labor/HHS/Ed. Subcommittee
U.S. House of Representatives
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member, House Appropriations
Labor/HHS/Ed. Subcommittee
U.S. House of Representatives
Washington, DC 20515

The Honorable Roy Blunt
Chair, Senate Appropriations
Labor/HHS/Ed. Subcommittee
United States Senate
Washington, DC 20510

The Honorable Patty Murray
Ranking Member, Senate Appropriations
Labor/HHS/Ed. Subcommittee
United States Senate
Washington, DC 20510

RE: Support Funding for the National Institutes of Health

Dear Chairman Cole, Chairman Blunt, Ranking Member DeLauro and Ranking Member Murray:

We write on behalf of the American Academy of Allergy, Asthma & Immunology (AAAAI) and the American College of Allergy, Asthma & Immunology (ACAAI) in support of an increase in funding for the National Institutes of Health (NIH) of at least \$2 billion above fiscal year (FY) 2017 appropriations, in order to account for inflation.

The AAAAI and ACAAI strongly urge appropriators to maintain the NIH's ability to conduct life-saving medical research and training. NIH, and in particular the National Institute of Allergy and Infectious Diseases (NIAID), the National Heart, Lung, and Blood Institute (NHLBI) and the National Institute of Environmental Health Sciences (NIEHS) are providing vital funding for medical research that could lead to life-improving treatments for individuals suffering from allergies, asthma, immunologic disorders and infectious diseases.

Each year, billions of dollars are spent treating the causes and symptoms of food, drug and skin allergy, immunodeficiency, and asthma. Through the work of NIAID, NHLBI and NIEHS and the research they are funding, we have the opportunity to identify and develop life-saving and life-improving treatments for these widespread chronic conditions.

This past October, NIAID researchers announced promising results from an NIH sponsored clinical trial on the efficacy and value of an intervention for treating children and young adults with peanut allergies. This January, an NIAID-sponsored expert panel issued clinical guidelines to help healthcare providers give parents and caregivers important information on early introduction of peanut-containing foods to infants to prevent the development of peanut allergy. These are the type of results the American people can expect from supporting NIH and their medical research mission. AAAAI and ACAAI hope the NIH will also begin work on implementing the recommendations contained within the Report from the NAID Workshop on Drug Allergy, which would advance our knowledge of the mechanisms, diagnosis, management, and prevention of drug allergy.

(more)

The AAAAI and ACAAI are professional organizations representing allergist/immunologists across the United States, Canada, and 72 other countries. Our members include board certified allergist/immunologists, other medical specialists, allied health and related healthcare professionals – all with a special interest in the research and treatment of patients with allergic and immunological diseases.

We sincerely thank the 217 bipartisan members of the House of Representatives who have already endorsed this request for at least \$36 billion in NIH funding for FY 2018 in a Dear Colleague letter dated March 31, 2017. The AAAAI and ACAAI call on appropriators to continue bipartisan support for the NIH as you embark on enacting appropriations bills for FY 2018.

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Peden', with a stylized flourish at the end.

David B. Peden, MD, MS, FAAAAI
AAAAI President

A handwritten signature in black ink, appearing to read 'S. Tilles', with a stylized flourish at the end.

Stephen A. Tilles, MD FACAAI
ACAAI President

United States Senate
WASHINGTON, DC 20510

June 1, 2016

The Honorable Sylvia Mathews Burwell
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Burwell:

We write to express our concerns about a recent proposal by U.S. Pharmacopeia (USP) to modify the guidelines that the Food and Drug Administration (FDA) has adopted for pharmaceutical compounding with respect to allergen extract compounding.

Allergen extract compounding is conducted by physicians as part of allergen immunotherapy (commonly referred to as “allergy shots”). Physicians prepare allergen extracts based on individual patients’ allergies, and allergists have developed specific expertise in how to prepare these allergen extracts for their patients that is not shared by other pharmaceutical compounders.

In 2015, FDA proposed guidelines for allergen extract compounding separate from the General Chapter 797 guidelines for sterile pharmaceutical compounding. More recently, USP has proposed removing this exemption for allergen extract compounding. This proposal has been made in the absence of any sentinel event or evidence presented by USP that infectious complications have occurred under the current policy. Physician and patient organizations have expressed great concern that this proposed change could make allergen extract compounding so complicated and expensive that it would virtually eliminate patient access to allergen immunotherapy.

A 2013 report by the Agency for Healthcare Research and Quality concluded that allergen immunotherapy (AIT) is both safe and effective.¹ Physicians have treated millions of patients with AIT for over a century, with no reported cases in the medical literature of patients developing an infection as the result of a non-sterile allergen extract. Thus, we respectfully request that you conduct an assessment to determine whether there is an evidence-based rationale for the proposed change.

We emphasize our strong support for the efforts of the FDA and USP to ensure the safety of pharmaceutical compounding, but question whether the data exist to support these changes to the standards for allergen extract compounding, as currently performed in physician offices.

In addition, we request your response to the following questions:

- It is our understanding that the USP proposal will make it impractical for allergists to compound immunotherapy prescriptions in their offices. In this case, how will physicians procure allergen extracts for individual patients? Are there a sufficient number of

¹ <http://www.ncbi.nlm.nih.gov/books/NBK133240/>

compounding pharmacies in the country that offer this service? Would this increase the cost of allergen extract preparation?

- Currently, Medicare and Medicaid cover the cost of in-office allergen extract compounding. It is our understanding that there is no billing code under which a physician can charge for extracts prepared by a third-party vendor. In this case, we presume that the cost of this service – currently covered by most medical insurance programs – would be passed on to the patient. How would physicians seek appropriate reimbursement for extracts prepared by a third-party vendor without an appropriate billing code? What would the impact of this change have on insurance coverage of allergen immunotherapy and patients' ability to access such treatment?
- There are several ongoing NIH-funded clinical trials involving allergen immunotherapy. Would the USP proposal have an adverse impact on this research?

Allergen immunotherapy has long been known to prevent the development of new allergies and asthma; it also reduces overall health care costs. It is essential that this proposed change be carefully examined for its potential impact on patients, which could significantly reduce access to allergen immunotherapy and increase costs, without any evidence that it would prevent infections that, to date, have not been documented in any patients.

Thank you for your attention to this important issue. If you have any questions, please contact Sara Mabry in Senator Casey's office at sara_mabry@casey.senate.gov. We appreciate your timely response to this letter.

Sincerely,



Robert P. Casey, Jr.
United States Senator



Mark Kirk
United States Senator



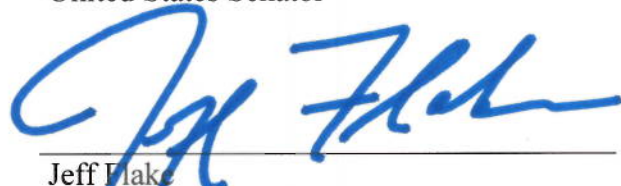
Benjamin L. Cardin
United States Senator



Richard Burr
United States Senator



Ron Johnson
United States Senator



Jeff Flake
United States Senator

Barbara Mikulski

Barbara Mikulski
United States Senator

Chuck Grassley

Charles E. Grassley
United States Senator

Charles Sch

Charles E. Schumer
United States Senator

Dick Durbin

Richard J. Durbin
United States Senator

Martin Heinrich

Martin Heinrich
United States Senator

Joni Ernst

Joni Ernst
United States Senator

John Barrasso

John Barrasso
United States Senator