



## SUPPORT THE FAMILY ASTHMA ACT (S. 2804)

### REQUEST

The American Academy of Allergy, Asthma & Immunology (AAAAI) asks that you **cosponsor the “Family Asthma Act” (S. 2804)** which would assist states in creating programs to better educate families on asthma management and prevention, and would improve asthma research and data collection to help target asthma interventions more effectively.

### SUMMARY

Amends the Public Health Service Act to require the Director of the Centers for Disease Control and Prevention (CDC) to collaborate with state and local health departments to conduct activities regarding asthma, including deterring the harmful consequences of uncontrolled asthma, and disseminating health education and information regarding prevention of asthma episodes and strategies for managing asthma; and develop state plans incorporating public health responses to reduce the burden of asthma, particularly regarding disproportionately affected populations.

The Family Asthma Act also would revise and expand requirements for asthma surveillance activities, as well as coordinate data collection activities and provide an assessment of current asthma-related activities along with recommendations.

### BACKGROUND

More than 25 million Americans suffer from asthma, and the number of people with asthma only continues to grow. The Centers for Disease Control and Prevention (CDC) report that asthma accounted for approximately 480,000 hospitalizations and 2,100,000 visits to hospital emergency departments in 2009. The annual cost of asthma to the U.S. is approximately \$56 billion, including \$5.9 billion in indirect costs from lost productivity. The CDC reports that 10.5 million school days and 14.2 million work days are missed annually as a result of asthma.

The disease kills 3,400 people each year, and is responsible for an additional 7,000 deaths annually as a result of asthma related complications. There is no cure for asthma, but once it is properly diagnosed and a treatment plan is in place patients are able to better manage their condition and improve their quality of life.

A board certified allergist/immunologist (AI) is specially trained to diagnose, treat and manage allergies, asthma and immunologic disorders ranging from the very common to the very rare, spanning all ages and encompassing various organ systems. Training involves at least an additional nine years of training beyond a bachelor’s degree, including at least two years of study, called a fellowship, in an AI training program.

A board certified allergist/immunologist is the best-qualified physician to diagnose and treat asthma. S. 2804 would bring together the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the asthma community to decrease asthma morbidity, mortality, and prevalence while identifying successful asthma interventions and recommendations for future research.



## SUPPORT ASTHMA MANAGEMENT PLANS IN SCHOOL ACT (H.R. 1007)

### REQUEST

The American Academy of Allergy, Asthma & Immunology (AAAAI) asks that you **cosponsor the “Asthma Management Plans in School Act” (H.R. 1007)** which would provide grants to schools for the development of asthma management plans and the purchase of asthma medications and devices for emergency use, as necessary.

### SUMMARY

Amends the Elementary and Secondary Education Act of 1965 to authorize the Secretary of Education to award grants to schools that are receiving part A title I school improvement funds (or to local health or education departments if they routinely carry out these activities) and are located in areas that have a high prevalence of asthma. The grants will assist schools in developing and implementing asthma management plans and assist with the purchase of asthma inhalers, nebulizer machines, valved holding chambers (VHCs), spacers, auto-injectable epinephrine, and other supplies necessary for the relief and treatment of asthma-affected students. The bill requires grantees to find innovative ways to encourage rapid bidirectional communication between schools and students' physicians and students' adherence to asthma treatment plans, and to ensure that they have on staff a nurse or individual who is trained to administer emergency asthma care.

### BACKGROUND

The most important part of managing asthma is to be very knowledgeable about how and when asthma causes problems, how some of the triggers can be avoided and how to use medications. The causes of asthma and best treatment may be quite different from one child to another. An asthma management plan outlines what medications to take, and when and how to increase the doses or add more medication if needed. The scientific knowledge about asthma and its therapy is constantly changing, so an ongoing relationship with the treating physician and an up-to-date management plan is critical. A board certified allergist / immunologist (AI) is specially trained to diagnose, treat and manage asthma. It is critical that this partnership be maintained in developing an asthma management plan.

Recently, data analysis from 2012/2013 on more than 400,000 Chicago kids, ages 3 through 18, including 18,287 with asthma, found that only a quarter of the asthmatic students had a 504 Plan on file at school.<sup>1</sup> A key problem is that if a school doesn't have an asthma management plan for a child, there is little they can do for a child suffering an asthma attack. They cannot provide medication, even if they have it, without parental authorization. A management plan, communication with the physician and the ability for a school nurse to administer a rescue inhaler can mean the difference between life and death.

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<sup>1</sup> Asthma and Food Allergy Management in Chicago Public Schools

Ruchi S. Gupta, Victoria Rivkina, Lilliana DeSantiago-Cardenas, Bridget Smith, Blair Harvey-Gintoft, and Stephanie A. Whyte  
Pediatrics peds.2014-0402; published ahead of print September 8, 2014, doi:10.1542/peds.2014-0402



## SUPPORT H.R. 3742, THE ANTIBIOTIC DEVELOPMENT TO ADVANCE PATIENT TREATMENT (ADAPT) ACT

### REQUEST

The American Academy of Allergy, Asthma & Immunology (AAAAI) asks that you **cosponsor the “Antibiotic Development to Advance Patient Treatment (ADAPT) Act” (H.R. 3742)** which would incentivize antibiotic research and development (R&D) by addressing a regulatory hurdle related to clinical trial design for antibacterial or antifungal drugs that is intended for treatment of a serious or life-threatening disease or condition to treat a limited population of patients for which there is an unmet medical need. Maintaining a robust antibiotic pipeline is important for individuals with allergies to medications (such as penicillin) and those with compromised immune systems. A board certified allergist/immunologist (AI) is specially trained to diagnose, treat and manage allergies, asthma and immunologic disorders ranging from the very common to the very rare, spanning all ages and encompassing various organ systems. Appropriate use of antibiotics is critical to slow the growth of resistance. AI physicians can help guide appropriate use by testing patients for allergies and ensuring that patients with allergies to medications receive the most appropriate antibiotic.

### SUMMARY

The ADAPT Act builds on the Generating Antibiotic Incentives Now (GAIN) Act, enacted by the 112th Congress. ADAPT would provide additional incentives and help to advance antibiotic drug development by establishing a new Food and Drug Administration (FDA) pathway for antibiotics and antifungals that permits the agency to approve drugs aimed at treating emerging threats in limited and specific populations. This will accelerate development of new treatments, which bolsters public health and does not diminish the FDA standards of evidence for safety and effectiveness. The ADAPT Act also strengthens monitoring by the Centers for Disease Control and Prevention (CDC) of resistance and the use of antibiotics to treat serious and life threatening infections and making these data publically available for providers, hospitals, and academics. Finally, it streamlines the process by which the FDA updates susceptibility test interpretive criteria (breakpoints) so that up-to-date and cutting edge data are available to health care providers in a timely fashion.

### BACKGROUND

According to the CDC, approximately 23,000 Americans will die this year due to antibiotic-resistant infections. The economic costs of antibiotic resistance are high as well. Drug-resistant bacterial infections cost the U.S. health care system an estimated \$20 billion annually (including 8 million additional hospital days) and \$34 billion in societal costs.

Antibiotics are often not economically feasible for companies because they must be used infrequently to protect against the development of resistance, are often priced low, and are used for short durations. In 1990, there were almost 20 pharmaceutical companies with large antibiotic research and development (R&D) programs. Today, there are only two or three large companies with strong and active programs and only a small number of companies have more limited programs.



## SUPPORT THE PATIENTS' ACCESS TO TREATMENTS ACT or "PATA" (H.R. 460)

### REQUEST

The American Academy of Allergy, Asthma & Immunology (AAAAI) asks that you **cosponsor the "Patients' Access to Treatments Act" (PATA), H.R. 460** which would limit co-payment, coinsurance, or other cost-sharing requirements for prescription drugs in a specialty drug tier to the dollar amount (or its equivalent) applicable to prescription drugs in a non-preferred brand drug tier.

### SUMMARY

Amends the Public Health Service Act to establish cost-sharing limits for health plans that cover prescription drugs and use a formulary or other tiered cost-sharing structure. Specifically, the bill limits cost-sharing requirements applicable to medications in a specialty drug tier (typically Tier IV or higher) to the dollar amount applicable to drugs in a non-preferred brand drug tier (typically Tier III). H.R. 460 will enable patient access to treatments, reduce disability and constrain health care costs.

### BACKGROUND

Traditionally, commercial health insurers have charged fixed co-pays for different tiers of medications: generics (Tier I), name brands (Tier II), and off formulary brand medications (Tier III). As an example, the co-pays might be set at \$10/\$20/\$50 for the three tiers.

Some commercial health insurance policies are now moving vital medications (mostly biologics such as immunoglobulin which primary immunodeficient patients rely on) into "specialty tiers" that utilize high patient cost-sharing methods. This "fourth tier (IV)" is now commonly requiring patients to pay a percentage of the actual cost of these drugs – from 25% to 33% or more, often costing hundreds of dollars, even thousands of dollars, per month for a single medication – rather than a fixed, flat dollar co-payment. These practices are placing medically necessary treatments out of reach of average Americans. A board certified allergist/immunologist (AI) is specially trained to diagnose, treat and manage allergies, asthma and immunologic disorders ranging from the very common to the very rare, spanning all ages and encompassing various organ systems. AI physicians are seeing more of their patients struggle with growing out-of-pocket costs or insurance plans that do not cover medically necessary medications at all, even epinephrine to treat serious food and other allergic reactions. Frustrating to all, these coverage policies can change monthly making it difficult for physician and patient to determine whether something is covered and at what cost to the patient.



## Medicare IVIG Demonstration Project

Congress passed the Medicare IVIG Access Act with overwhelming bipartisan support (P.L. 112-242) at the close of the 112<sup>th</sup> Congress.

### **SUMMARY**

The Medicare IVIG Demonstration is authorized under Title I, section 101 of the “Medicare IVIG Access and Strengthening Medicare and Repaying Taxpayers Act of 2012” (P.L. 112-242). This is a three year demonstration and provides for enrollment of up to 4,000 Medicare beneficiaries. Under the demonstration there will be a per-visit payment amount for items and services needed for the in-home administration of intravenous immune globulin (IVIG) based on the national per visit low-utilization payment amount (LUPA) under the prospective payment system for home health services.

### **STATUS**

The Centers for Medicare and Medicaid Services (CMS) successfully completed its initial open enrollment period for the IVIG Demonstration on September 12<sup>th</sup>. As a result, starting on October 1<sup>st</sup>, several hundred Medicare beneficiaries with primary immune deficiency disease (PI) from more than 40 states began receiving their immunoglobulin medication in their home. New applications for participation in the IVIG Demonstration continue to be accepted on a rolling basis.

Participation in the benefit requires physician sign off. A board certified allergist/immunologist (AI) are the medical specialty trained to treat this rare disease patient population and determine if they are appropriate candidates for the Medicare home infusion benefit.

### **BACKGROUND**

The Medicare Modernization Act (MMA) of 2003 created a benefit for Medicare beneficiaries with primary immunodeficiency (PI) diseases to receive IVIG infusions in the home, in addition to the other covered settings, such as hospital outpatient departments, infusion clinics and physician offices. The intent was to give Medicare PI patients the choice to avoid the hospital when their immunity is at the lowest. However, the 2003 law as written only provided coverage and reimbursement for the immunoglobulin product, not the items and nursing services needed to infuse it. A separate provision in the MMA changed the reimbursement methodology for IVIG and other Part B drugs. The unintended consequence of this change was to reduce IVIG reimbursement to the point where it was less than the cost of infusing IVIG in many settings; essentially rendering the IVIG home infusion provision an “empty benefit” as patients were left to cover the unreimbursed nursing costs. The Medicare IVIG Access law was championed by Rep. Kevin Brady (R-TX), Rep. Doris Matsui (D-CA), Sen. Lamar Alexander (R-TN) and former Sen. John Kerry (D-MA). It allows Medicare PI patients to receive home infusions of intravenous immunoglobulin replacement therapy which provides antibody replacement for individuals with primary immunodeficiency (PI) diseases -- a group of over 185 genetic or intrinsic disorders in which part of the body’s immune system is missing or does not function properly.



## REPEAL AND REPLACE SUSTAINABLE GROWTH RATE (SGR) PHYSICIAN PAYMENT FORMULA

### REQUEST

The American Academy of Allergy, Asthma & Immunology (AAAAI) asks that Congress **repeal the Sustainable Growth Rate (SGR) and enact permanent physician payment reform** during the lame duck session or early in the 114<sup>th</sup> Congress.

### SGR REPLACEMENT

Since 2002, the SGR formula has called for ever-increasing cuts to Medicare physician reimbursement, which threatens the viability of many physicians' practices and imperils patient access to physicians. Congressional, short-term overrides of these cuts have exacerbated the underlying issue by adding to the overall cost of a permanent solution. The latest patch, which overrides the latest cut until April 1, 2015, was preceded by significant progress towards bipartisan, bicameral permanent reform, and the AAAAI strongly urges Congress to continue building on this momentum so that a permanent solution can be enacted in a lame duck session before the end of the 113th Congress. The AAAAI is on record supporting the "SGR Repeal and Medicare Provider Payment Modernization Act of 2014," which provides a permanent repeal of the SGR while addressing many physician concerns such as providing a five-year period of stable updates, preserving fee-for-service as a continued option, implementing a streamlined quality improvement program based on benchmarks achievable by all physicians, and allowing for physician and specialty society inclusion in the development of new performance measures and payment systems.

### VALUE-BASED PAYMENT MODIFIER (VBM)

In linking physician payment to quality care, Congress should **use positive financial incentives rather than penalties and withholds**. In the last year alone, CMS has doubled the maximum penalties associated with the VBM program, specifically, and increased the pool of affected physicians by approximately 50 percent, leaving physicians with very little time to prepare to avoid penalties. The VBM penalties, when combined with penalties associated with other programs, such as the Physician Quality Reporting System (PQRS), and the Electronic Health Record (EHR) Incentive Program, could reduce physician reimbursement by almost ten percent. Congress should consolidate existing quality reporting programs-- which are administratively burdensome, duplicative, and rely on metrics of questionable value—and repeal penalties associated with each. Physicians must be given the flexibility to demonstrate quality improvement in a way that is most relevant to their practice, most meaningful to their patient populations, and deemed appropriate by medical societies.

### BACKGROUND

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## ABOUT THE AMERICAN ACADEMY OF ALLERGY, ASTHMA & IMMUNOLOGY

The American Academy of Allergy, Asthma & Immunology (AAAAI) represents a diverse group of more than 6,800 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.

Recent AAAAI advances related to improving practice and outcomes in the care of allergy, asthma and immunology patients include Asthma IQ and the AAAAI Quality Clinical Data Registry. Asthma IQ is a web-based clinical decision support tool provided free to users that helps allergists/immunologists as well as primary care physicians learn about the EPR-3 asthma guidelines and deliver high quality, evidence-based care to their patients with asthma.

The Allergy, Asthma and Immunology Quality Clinical Data Registry (QCDR) is a CMS-approved QCDR registry for the 2014 Physician Quality Reporting System (PQRS) program year. The AAAAI QCDR is the only PQRS reporting option with allergy immunotherapy measures available for reporting and is designed as a practice improvement tool. The AAAAI QCDR was developed to increase provider participation in CMS quality reporting programs and increase guideline-based practice for improved patient outcomes.

The AAAAI is proud to produce the ***Journal of Allergy and Clinical Immunology (JACI)***, the most cited journal in the field, as well as ***JACI: In Practice***, with an emphasis on practical clinical research and the latest recommendations for diagnosis and treatment.