Allergy & Asthma Network ("Network") is the nation’s leading voice and patient advocate for more than 50 million Americans with allergies and 22 million with asthma. For 32 years, the Network has worked to end needless death and suffering due to asthma, allergies and related conditions through outreach, education, advocacy and research.

Asthma remains one of the most serious chronic diseases and costly health issues ($80 billion annually in direct and indirect healthcare costs) in the United States. Approximately 3,600 Americans die each year due to asthma. The disease has greater impact on vulnerable populations, including children and older adults as well as those living with other diseases. Populations that are low-income and some ethnic groups also have a higher rate of diagnosed asthma, increased hospitalizations and deaths.

Of the millions of Americans living with allergies to the environment, food, insect venom, medications and latex, there are 15+ million at risk for a severe allergic reaction, or anaphylaxis. Symptoms of anaphylaxis vary and can include hives, coughing, shortness of breath, tongue and throat swelling, vomiting, stomach pain and shock. Severe anaphylactic reactions can lead to death. There are approximately 700 deaths annually due to anaphylaxis, and children and adolescents are among those most at risk.

Together with patients, families, healthcare professionals and industry partners, the Network seeks to ensure that federal and state laws, policies, regulations and resources support our role in achieving optimal health outcomes for people with asthma and allergies. The following pages provide details on the key advocacy issues for Allergy & Asthma Day Capitol Hill.

For more information about Allergy & Asthma Network contact us at 703-641-9595 or www.AllergyAsthmaNetwork.org.
ADVOCACY ISSUES SUMMARY

ACCESS TO CARE

- Maintain adequate coverage for individuals who rely on Medicaid.
- H.R. 2285, Implementation of School-Based Health Management Programs.
- H.R. 2077, Transparent process for medications subject to step therapy.
- H.R. 4, Access to safe and effective medications in aircraft emergency medical kits.
- Use of telemedicine technologies to provide respiratory care services.

AFFORDABLE MEDICATIONS AND TREATMENTS

- Reduction of prescription drug costs for patients particularly those with chronic or life-threatening conditions.
- Provide a separate HCPCS billing code and reimbursement in Medicare Part B for each biosimilar biologic product.

ASTHMA AND ALLERGY FEDERAL FUNDING

- Continue funding in FY2019 for the CDC’s National Asthma Control Program at $30 million.
- Continue funding in FY2019 for EPA’s research, education and outreach initiatives that address indoor and outdoor environmental factors that trigger asthma in communities and schools.
- Continue funding in FY2019 for NIH research programs (NHLBI’s National Asthma Education and Prevention Program and NIAID) for allergy, asthma and related conditions.

HEALTH EQUITY

- Development of health equity interventions to support better health outcomes for patients in areas including:
  - Environment (indoor and outdoor)
  - Housing
  - Transportation
  - Education
  - Language and Culture

FOOD PRODUCT LABELING

- H.R. 5425, Updates food packaging requirements and adds sesame on ingredient labels of processed foods.
- Require manufacturers to list potential food allergen cross-contact on food package labels.

USP PHARMACEUTICAL COMPOUNDING: STERILE PREPARATION GUIDELINES – CHAPTER 797

Maintain the current USP allergy exception for allergen extracts which requires mixing to be done with aseptic technique, but without the environmental and other controls required for more dangerous compounding drugs.
ACCESS TO CARE

Access to affordable, high-quality healthcare and safe and effective medications is important for all Americans, especially for those with chronic, life-threatening illnesses (e.g., asthma and severe allergies). Preventive care and medical treatment options are essential to helping patients live a full life.

MEDICAID

Medicaid is the largest health insurance program in the U.S., covering more than 62 million Americans, including millions of the poorest individuals and families in the nation. Medicaid also serves as a critical source of coverage for minority children. In some states, more than half of all children with asthma rely on Medicaid for their health coverage. One in three children with asthma lives in poverty, and the rate of asthma is significantly higher among African-American and Puerto Rican children – leading to dramatic health disparities for our most vulnerable citizens.

DISEASE MANAGEMENT

Despite the availability of various treatments and disease management guidelines, there are patients with uncontrolled asthma, which can impact their quality of life. The development of asthma management plans in coordination with the patient, physician, caregiver and school personnel (if applicable) can lead to reduced risk of asthma episodes and improved health outcomes.

SCHOOL-BASED RESPIRATORY HEALTH MANAGEMENT ACT (H.R. 2285) increases grant preference to states which implement comprehensive school-based reversible lower airway disorders (e.g., asthma) and allergy management programs that include student action plans, and education and training for school staff to administer medications in an emergency. This bill would better equip schools to help students manage their disease.

Note: The Asthmatic Schoolchildren's Treatment and Health Management Act signed into law in 2004 led to legislation in all 50 states ensuring schoolchildren with asthma had the right to self-carry and administer their quick-relief inhaler at school. Schools across the country are also stocking emergency supplies of inhalers for students who forget their inhaler or use one so infrequently they do not have it at school. Implementing management plans and ensuring school staff members are prepared are the best defenses in assisting children with asthma.

MEDICATION ACCESS

Step therapy is a practice health insurance plans use to manage the cost of medications. These insurance policies require the least expensive drug to be prescribed to a patient first, rather than the medicine originally prescribed by the doctor. This practice can result in serious negative consequences for consumers and the public health system. By limiting the medication options, both doctors and patients are forced to compromise their treatment decisions in a way that is dangerous, time consuming and more expensive in the long-term.

RESTORING THE PATIENT'S VOICE ACT (H.R. 2077) provides a clear and transparent process to seek exceptions and approvals for medications subject to step therapy review by health insurance plans and establishes a reasonable and clear timeframe for overriding decisions.
Currently, only a handful of airline carriers stock epinephrine auto-injectors on board their flights. Airlines should carry no fewer than two packs of epinephrine auto-injectors as treatment for anaphylaxis and provide crewmember training so they know how to recognize an allergic reaction and administer an epinephrine auto-injector.

**FEDERAL AVIATION ADMINISTRATION (FAA) REAUTHORIZATION (H.R. 4)** in the House of Representatives includes language for the FAA Administrator to evaluate and revise regulations regarding aircraft emergency medical kits to meet the emergency medical needs of children. The Senate bill (S.1405) does not include this language.

**TELEMEDICINE**

For Americans living with asthma, allergies and related conditions, telemedicine would be an effective way to provide disease education and improved disease management. This is particularly true in rural areas, where visiting a physician’s office could require traveling lengthy distances. All Americans living with chronic respiratory illness can experience improved health outcomes using modern technologies such as telemedicine as a complement to existing healthcare resources. This provides a valuable – and cost-effective – way for people to get necessary treatment.

**ALLERGY & ASTHMA NETWORK SUPPORTS**

- Maintaining adequate coverage for individuals who rely on Medicaid.
- H.R. 2285, Implementation of School-Based Health Management Programs.
- H.R. 2077, Transparent process for medications subject to step therapy.
- H.R. 4, Access to safe and effective medications in aircraft emergency medical kits.
- Use of telemedicine technologies to provide respiratory care services.
AFFORDABLE MEDICATIONS AND TREATMENTS

MEDICATIONS

Access to affordable medicines is critical as the rising costs of prescription drug prices puts Americans at risk for poorer health outcomes, especially those with chronic and life-threatening conditions such as asthma and allergies. Lack of access to affordable medicines has led to patients not filling a doctor’s prescription, reducing the dosage to make a supply last longer, buying medicines from foreign countries or substituting alternative therapies.

TREATMENT OPTIONS AND PROCEDURES

As medicine and technology advance, more effective treatment options and procedures (e.g., biosimilar biologics) are available for patients, particularly those with severe chronic conditions. To facilitate effective pharmacovigilance, support appropriate patient care and facilitate reimbursement, the Centers for Medicare and Medicaid Services (CMS) should provide for a separate Healthcare Common Procedure Coding System (HCPCS) billing code and reimbursement for each biosimilar biologic product.

For Medicare and other health insurance programs to ensure that reimbursement claims are processed in an orderly and consistent manner, standardized coding systems are essential. CMS developed HCPCS to facilitate timely and accurate processing of reimbursement claims. The Affordable Care Act created a novel and carefully balanced formula for reimbursing biosimilars compared to innovator biologics in Medicare Part B.

ALLERGY & ASTHMA NETWORK SUPPORTS

• Reduction of prescription drug costs for patients particularly those with chronic or life-threatening conditions.
• Provision of a HCPCS billing code and reimbursement in Medicare Part B for each biosimilar biologic product.
Federal programs at the Centers for Disease Control and Prevention, Environmental Protection Agency and National Institutes of Health support the 50+ million Americans with asthma, allergies and related conditions.

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

National Asthma Control Program

Asthma is a complex disease that requires a comprehensive approach and the “National Asthma Control Program” works to integrate and coordinate the public health response to asthma control. There are national and state-specific surveillance systems in place that allow officials to track and better understand asthma trends – and ultimately enable decision-makers to focus resources on strategies that work and populations that are most in need. Environmental measures are a strong approach to put in place to reduce exposure to indoor and outdoor air pollutants. Schools have established appropriate programs and policies to reduce the number of students experiencing asthma attacks, as well as reduce the number of school days missed. While the prevalence of asthma has increased over the last 10 years, states participating in the program are showing that more people with asthma are able to control their disease through self-management, education and appropriate healthcare services for the treatment of asthma.

ENVIRONMENTAL PROTECTION AGENCY (EPA)

Asthma Initiatives

Many chronic respiratory conditions like asthma affect low income and minority communities and environmental pollutants in the air, homes and schools can cause and exacerbate asthma symptoms. EPA works to improve public health in communities and schools by implementing initiatives (e.g., Health Communities Grant Program) that address pollutants and perform periodic reviews of air quality standards.

Together with national, state and local stakeholders, EPA works to manage environmental asthma triggers through direct health professional training, deliver comprehensive asthma care in the community through education and outreach, and via an online interactive asthma community, AsthmaCommunityNetwork.org, where effective program strategies are shared to advance asthma care. Research shows investments in interventions are fundamental for effective asthma management resulting in improved health outcomes and reduced healthcare costs.

NATIONAL INSTITUTES OF HEALTH (NIH)

National Heart, Lung and Blood Institute (NHLBI) - National Asthma Education and Prevention Program (NAEPP)

The National Institutes of Health (NIH) National Heart, Lung and Blood Institute’s (NHLBI) lung disease program supports research on the causes, diagnosis, treatment and prevention of lung diseases, including asthma and chronic obstructive pulmonary disease (COPD). As a result of NHLBI research, people with asthma now have more treatment and prevention options.
The NHLBI’s National Asthma Education and Prevention Program (NAEPP) engages local, state, regional and national stakeholders (including medical associations, voluntary health organizations, and community programs) to improve asthma control for patients based on evidence-based recommendations, share best practices and resources, and identify new directions and learning opportunities. As a result, there is a more inclusive and standardized approach to best practice across the country. A comprehensive clinical guideline on asthma was released by NAEPP [Guidelines for the Diagnosis and Management of Asthma] to emphasize the importance of effectively providing quality care for patients with asthma.¹

**National Institute of Allergy & Infectious Diseases (NIAID)**

The National Institute of Allergy & Infectious Diseases (NIAID) conducts and supports research to increase understanding, improve techniques of diagnosis, treatment and prevention of allergic diseases such as asthma, environmental allergies, food allergies and eczema (atopic dermatitis).

**ALLERGY & ASTHMA NETWORK SUPPORTS**

- Continued funding in FY2019 for the CDC’s National Asthma Control Program at $30 million.
- Continued funding in FY2019 for EPA’s research, education and outreach initiatives that address indoor and outdoor environmental factors that trigger asthma in communities and schools.
- Continued funding in FY2019 for NIH research programs (NHLBI’s National Asthma Education and Prevention Program and NIAID) for allergy, asthma and related conditions.

Health disparities (e.g., access to care, poverty, environmental hazards, education inequities, behavioral issues) cross ethnic and socioeconomic groups and impact individual health and well-being. Asthma and allergy rates are higher in poor urban areas and more common in African-American, Native American and Hispanic children, according to the Centers for Disease Control and Prevention (CDC) National Center for Health Statistics. Proven intervention strategies (e.g., programs, services and policies) are needed to develop successful health equity interventions.

Asthma and allergy disparities occur due to increased exposure to environmental allergens and irritants that trigger asthma symptoms, such as mold, dust mites, cockroaches and mice, and cigarette smoke. Often these triggers are more common in urban areas with substandard housing and vehicular exhaust from living near highways.

Poverty can affect access to preventive medications and healthcare. Limited or lack of transportation results in patients rescheduling or missing their medical appointments, delaying their care, and forgoing or delaying medication use. As a result, those patients do not manage their medical conditions properly, leading to poorer health outcomes.

Language and cultural differences can be a barrier and education inequities can lead to a lack of basic knowledge and understanding of the disease, impacting patient adherence to treatment plans and use of prescribed medications.

**HEALTH EQUITY**

Development of health equity interventions to support better health outcomes for patients in areas including:
- Environment (indoor and outdoor)
- Housing
- Transportation
- Education
- Language and Culture
FOOD PRODUCT LABELING

SESAME

More than 15 million Americans are living with food allergies, including 6.1% of children. Sesame allergy has increased over the years in part due to the growing number of products containing sesame seeds and sesame oil – foods, cosmetics, lotions and pharmaceutical items.¹

The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) became effective in 2006 and governs how the eight major food allergens: milk, egg, peanut, tree nuts, soy, wheat, fish and crustacean shellfish are represented on packaged foods in the U.S. Unfortunately, sesame is not recognized as a major food allergen in the U.S. like Canada, the European Union, Israel, Australia, New Zealand, and many others.

In 2016, a report by the National Academy of Sciences² recommended that sesame be listed as a major food allergen and identified on food labels. While allergen avoidance is the key to managing a food allergy, successful avoidance requires individuals to have accurate information on the ingredients and possible allergenic contaminants in food labeling.

FOOD LABELING MODERNIZATION ACT (H.R. 5425) would update food package labeling requirements, and update ingredient list on packaged foods adding “sesame” among other labeling requirements for consumers to evaluate products and make healthier and safer food choices.

CROSS-CONTACT

While FALCPA makes it easier for people with food allergies to avoid packaged products that contain food allergens, manufacturers are not required to list major allergens that may be present due to unintentional “cross-contact” during processing. Cross-contact happens when a small amount of a food allergen gets into another food accidentally, or when it is present in saliva, on a surface or on an object. This small amount of an allergen could cause an allergic reaction.³ Individuals affected by food allergies need to be able to identify potential allergens and not solely rely on contacting the manufacturer to determine whether a food is safe.

ALLERGY & ASTHMA NETWORK SUPPORTS

- H.R. 5425, Updates food packaging requirements and adds sesame on ingredient labels of processed foods.
- Requiring manufacturers to list potential food allergen cross-contact on food package labels.


Millions of Americans who suffer from allergies benefit from allergy immunotherapy each year. There are more than 4,200 allergists nationally who prepare and provide allergy immunotherapy extracts to their patients. It is estimated more than 16 million allergy immunotherapy injections are administered annually in the United States.

Background

In November 2015, U.S. Pharmacopeia (USP) announced proposed changes to Chapter 797 on sterile compounding that would remove the special exception rules for preparation of allergen extracts. USP’s proposal, if adopted, would make it difficult, if not impossible, for most doctors to prepare allergen immunotherapy extract in their offices. This could result in millions of patients losing access to appropriate care. Furthermore, USP has provided no scientific data to support its position that more stringent rules are required.

The U.S. Food and Drug Administration (FDA) already requires that all allergen extracts or “concentrates” be combined in sterile vials using sterile syringes – these sterile compounding standards are specific to allergen extracts. In addition, aseptic technique is followed, and the patient-specific vials are labeled and stored in refrigerated conditions. To the extent patient safety issues have come up with respect to allergen extracts, the adverse events are related to reactions to the antigens themselves and not the presence of contaminants in the antigen preparations.

Allergy immunotherapy is a proven, clinically effective treatment for individuals with allergic rhinitis, allergic asthma and hypersensitivity to insect stings. The efficacy of allergy immunotherapy is well established in medical literature.

ALLERGY & ASTHMA NETWORK SUPPORTS

Maintaining the current USP allergy exception for allergen extracts which requires mixing to be done with aseptic technique, but without the environmental and other controls required for more dangerous compounding drugs.

1 U.S. Pharmacopeia (USP), [http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision](http://www.usp.org/usp-nf/notices/general-chapter-797-proposed-revision)