



President Joseph Biden
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Vice President Kamala Harris
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

July 15, 2022

Dear President Biden and Vice President Harris:

On behalf of the Asthma and Allergy Foundation of America (AAFA) and the 32 million Americans with food allergies, I want to thank you for the opportunity to share our policy priorities for the White House Conference on Hunger, Nutrition and Health. AAFA is the leading patient organization advocating for people with asthma and allergies, and the oldest asthma and allergy patient group in the world.

We strongly applaud the Administration's efforts to address the interrelated issues of hunger, nutrition, and health. For our patient community living with food allergies, accessing nutritious and safe foods is crucial. Our comments detail our community's experience and federal policy needs to keep children and adults with food allergies safe.

The Impact of Food Allergies in the United States

According to the most recent data, at least ten percent of adults have food allergies.¹ The level is nearly as high among children, at 9.3 percent, reflecting an increase in prevalence over time.² A recent study found that across all age groups, the rate of emergency room visits for food-related anaphylaxis increased by 124% from 2005 through 2014.³ Food-related anaphylaxis is associated with deaths of children and adults, particularly in cases where epinephrine is not available.⁴

Unfortunately, there are significant racial and ethnic disparities in the prevalence and impact of food allergies. Overall, Black children are 7% more likely to have food allergies than white children, and Black children with food allergies are more likely than white children to die from anaphylaxis. Children of Pacific Islander, Native Hawaiian or Asian heritage are 25% more likely than white children to have food allergies. Meanwhile, lower-income people and people in racial and ethnic minority groups are less likely to be able to access nutritional food overall and face greater barriers in accessing allergy-safe food.

¹ Gupta et al., Prevalence and Severity of Food Allergies Among US Adults. *JAMA Netw Open*. 2019 Jan 4;2019.

² Gupta R, Warren C, Blumenstock J, Kotowska J, Mittal K, Smith B. The prevalence of childhood food allergy in the United States: An update. *Ann Allergy Asthma Immunol* (2017).

³ Motosue et al., "Increasing Emergency Department Visits for Anaphylaxis, 2005-2014." *J Allergy Clin Immunol Pract*. 2017 Jan - Feb;5(1):171-175.

⁴ Bock et al., "Further fatalities caused by anaphylactic reactions to food, 2001-2006." *J Allergy Clin Immunol*. April 2007 Volume 119, Issue 4, Pages 1016-1018



Many Americans are also managing other lesser-known but highly challenging allergic conditions, Eosinophilic Esophagitis (EoE) and Food Protein-Induced Enterocolitis Syndrome (FPIES). EoE is an allergic condition, typically triggered by either food or pollen, that causes painful swelling in the esophagus and can hinder a person's ability to eat, impacting their weight and growth (especially in children). FPIES, experienced primarily by young children, is a gut-mediated immune reaction to certain foods in which exposure can lead to extremely severe vomiting and diarrhea. Infants and children with severe milk allergy, EoE, or FPIES often need specialized formula or foods, and their families have therefore been particularly hard hit by the infant formula shortage which included amino acid formulas used to treat these conditions.

Federal Policy Recommendations

AAFA supports the following federal policy options to improve the health and safety of people with food allergies and related conditions:

Support the Food Labeling Modernization Act

The Food Labeling Modernization Act, or FLMA (H.R.4917/S.2594), would make important updates to how food labels promote nutrition and health. One of the provisions most important to people with food allergies would require that label information, including allergen information, be made available when food is sold online. For most people with food allergies, the only way to prevent reactions is to avoid known allergens. Under the Food Allergen Labeling and Consumer Protection Act (FALCPA), FDA has promulgated regulations that require clear, plain-language labeling of certain food allergens in packaged foods. However, current law does not extend to online marketing and sale of food products. The FLMA would also require clearer disclosure of gluten-containing grains, an important step to protect the health of people living with celiac disease. Overall, FLMA will make nutrition information clearer and more accessible, promoting health among consumers with and without food allergies.

Support the Medical Nutrition Equity Act

Millions of children and adults with digestive or metabolic disorders – including some with EoE or FPIES - require specifically formulated medically necessary foods to prevent severe health outcomes. However, these foods (which often come in the form of formula), supplements, or individual amino acids are often prohibitively expensive and are inconsistently covered by insurance. The Medical Nutrition Equity Act (S.2013/H.R. 3783) would expand coverage for these foods in Medicaid, Medicare, Tricare, FEHBP, and private insurance.



We have attached to this letter several constituent stories about the importance of the coverage of medically necessary foods.

Increase Funding for Food Allergy Research

AAFA supports maximizing funding for basic, clinical, preventive, and health services research. This effort includes supporting increased research funding for the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC) and other agencies that conduct research on asthma and allergic diseases.

AAFA helped advance the passage of the Food Allergy Safety, Treatment, Education and Research (FASTER) Act of 2021. While the law makes sesame the 9th major food allergen recognized in the United States, it also requires the U.S. Department of Health and Human Services to prepare a report on Federal activities related to surveillance and data collection on the prevalence of food allergies and severity of allergic reactions, development of effective food allergy diagnostics, prevention of the onset of food allergies, and development of new therapeutics, as well as recommendations and strategies to expand, enhance, or improve federal food allergy activities. We urge the Administration to prioritize this important report and to expedite its release.

Federal agencies conduct invaluable research on behalf of patients with food allergies, although areas of weakness exist including a lack of robust surveillance data on allergy and food allergies:

- AAFA supports strengthening funding for NIH to research the prevention and treatment of food allergy more robustly. The National Institute of Allergy and Infectious Diseases (NIAID) is the lead institute at NIH conducting research on food allergies and must be adequately funded.⁵
- CDC does not adequately collect surveillance data on allergy, including food allergy. Currently, CDC only gathers surveillance data on “hayfever” and does so inconsistently. We urge CDC to strengthen data collection and analysis related to food allergy prevalence and type.
- AAFA supports robust funding for Defense Health Research Programs, including the Congressionally Directed Medical Research Programs (CDMRP). Since fiscal year (FY) 1992, Congress has appropriated funds to the Department of Defense (DOD) explicitly for use in conducting medical research. Since its inception,

⁵ The National Institute of Allergy and Infectious Diseases (NIAID). <https://www.niaid.nih.gov/>



annual congressional appropriations for CDMRP have grown from \$25 million in FY1992 to \$1.4 billion in FY2020.⁶ CDMRP views its role in the medical research community as a leader in advancing medical and scientific research and filling research gaps “by funding high impact, high risk and high gain projects that other agencies may not venture to fund.”⁷ Research dollars through this program should be used to support research on food allergy related issues.

Increase Funding for Nutrition Labeling Standards and Enforcement at FDA

AAFA supports increased appropriations for the FDA’s Center for Food Safety and Applied Nutrition, or CFSAN. CFSAN is the Center at FDA that conducts crucially important work on food labeling related to allergens. An increase in appropriations would support much needed enforcement of existing labeling requirements and effective implementation of the new allergen labeling requirement for sesame.

In addition, funding is needed to support other FDA allergen labeling work. AAFA has long been concerned about “precautionary allergen labeling” (PAL) used to make consumers aware of cross-contamination of foods with allergens during the food production and processing. PAL language can say “May contain...” or “Made on shared lines with...” This approach to labeling is not standardized (nor required) so consumers with food allergies avoid these foods because of cross contamination concerns.

AAFA’s survey of families managing allergies found that the lack of standardized regulation around precautionary allergen labeling leads to increased anxiety and fear among parents and makes it more challenging to navigate daily life with food allergies. Increased appropriations would help CFSAN initiate the research needed to identify an appropriate regulatory approach to precautionary allergy labeling in the U.S. This research would need to determine valid, evidence-based allergen thresholds and accurate information about the risk of allergens in ingredients. This type of evidence-based threshold exists for gluten, but for none of the major allergens.

⁶ Congressional Research Service, Congressionally Directed Medical Research Programs: Background and Issues for Congress, November 10, 2020.

⁷ Overview of the Congressionally Directed Medical Research Programs, available at <https://www.ncbi.nlm.nih.gov/books/NBK424514/>



Promote Food Allergy-Friendly Options for Child Nutrition Programs like the School Lunch program, WIC, and SNAP

A growing number of Americans have been turning to federal food assistance programs. These programs offer an opportunity to extend limited dollars. Yet, for families managing food allergies, these programs can result in potentially unsafe food choices.

Recommendations to improve these programs to better serve individuals with food allergies include:

- SNAP: As the largest federal nutrition assistance program, SNAP benefits are calculated based on factors including household size, but do not take into consideration the differences in food costs. For families managing food allergies, those costs can be considerable. Additional subsidies are needed for families with food allergies.
- WIC: Under the WIC program, the federal nutrition assistance program for pregnant, postpartum and breastfeeding women, infants and children up to age 5, eligible participants receive vouchers for food. Unfortunately, the food list is dominated by nearly all of the most common food allergens, which can create limitations for those trying to avoid unsafe foods. The WIC food package must include more allergy friendly food options and provide nutritional education modules focused on label reading and avoiding cross-contamination. The WIC program should develop nutrition education materials to support individuals with food allergies during pregnancy and in the postpartum period; infants impacted by prenatal food allergy exposure; and children with food allergies.

Other challenges exist in WIC as well. For example, children with EoE, a chronic disease driven by food allergens, often require an elemental diet. Elemental diets, also known as amino acid-based formulas, are classified as medical foods by the FDA. When food allergy is the suspected cause, an elemental diet removes all potential food antigens from the diet and supports nutrition through a hypoallergenic formula. Each state has the authority to determine which formulas their state offers through the WIC and Medicaid programs. Not all state formulas include the elemental formulas used to treat EoE nor do all states provide nutrition for children with EoE or multiple food allergies. A standardized list of medical foods for individuals with allergies should be available in all states.



- Child Nutrition Programs: A number of programs including the National School Lunch Program and School Breakfast Program, the Child and Adult Care Food Program, and the Summer Food Service Program provide healthy meals and snacks to eligible children. Unfortunately, unsafe practices for individuals with food allergies may occur to offset increases in food and labor costs, especially during summer when food accommodations may be rare for those with food allergies. AAFA urges the USDA to enforce strict standards year-round in these programs to ensure that children with food allergies receive appropriate and safe food. Children in these programs have a right to allergy-safe foods. When programs do not provide safe food, families must file a grievance to require a program to follow the law. The USDA should provide comprehensive education and outreach to families with food allergies to share information about their rights to allergy-safe foods in these programs and to provide information about available options for recourse. Additionally, food allergy training and certification for all local food service personnel working in these programs should be required. Training modules should be developed for personnel to prevent allergic reactions to food. Training modules could include best practices for communicating food allergen information in school menus, food products, and recipes and the appropriate responses to an allergic reaction to food.

Accessibility and Affordability of Epinephrine

Epinephrine is the only treatment for anaphylaxis and is only available with a prescription. Anaphylaxis is a severe and potentially life-threatening allergic reaction. Children and adults who have severe food allergies need epinephrine with them at all times to promptly treat anaphylaxis. Individuals and families managing food allergies often bear a heavy and rising cost burden for epinephrine auto-injectors (EAI)s.⁸

AAFA supports a number of policies that will strengthen accessibility and affordability of epinephrine, including:

- Promoting policies that increase access to epinephrine auto-injectors (EAI)s for all children and families with food allergies.

⁸ Pepper et al., “The High Cost of Epinephrine Autoinjectors and Possible Alternatives.” [J Allergy Clin Immunol Pract.](#) 2017 May - Jun;5(3):665-668.



- Supporting laws and policies that make EAIIs available in schools, childcare facilities, restaurants, planes, and other public places where food allergens may be present. These policies, typically at the state level, include laws permitting schools and other locations to keep a supply of “stock” epinephrine that can be used on any individual in case of an emergency; good Samaritan laws that limit liability for people who administer EAIIs; and laws providing for training of teachers or others who may be able to administer EAIIs.
- Supporting policies to bolster and maintain the national supply of epinephrine EAIIs, and to keep the food allergy community and other EAI users informed of the status of EAI shortages. AAFA encourages FDA to use all available regulatory tools to ensure the safety of EAI manufacturing, to minimize the impact of shortages on consumer access, and to bring alternative products to market as rapidly as possible. Additionally, AAFA supports policies that give consumers access to the EAIIs with which they are most comfortable. Any limitations on EAI type, whether in public or private insurance, should be eliminated in the context of a shortage.

Improve Menu Labeling

Restaurants are a common location for adverse reactions to foods and represent a significant proportion of food allergy fatalities.^{9,10} Many restaurants and restaurant workers are not aware of, or are not implementing, practices to improve food allergy safety.¹¹ Making restaurants safer could reduce preventable reactions, including death, and allow people with food allergies to engage more fully in social activities with their family and friends with less fear and stress.

AAFA supports improved food allergy labeling on menus. Just as FDA requires nutrition information on menus through the “Nutrition Labeling of Standard Menu Items in

⁹ Wanich, N., C. Weiss, T. J. Furlong, and S. H. Sicherer. 2008. Food allergic customer (FAC) experience in restaurants and food establishments. *J. Allergy Clin. Immunol.* 121:S182.

¹⁰ Weiss, C., and A. Munoz-Furlong. 2008. Fatal food allergy reactions in restaurants and food-service establishments: strategies for prevention. *Food Prot. Trends* 28:657–661.

¹¹ Young et al., “A systematic review and meta-regression of the knowledge, practices, and training of restaurant and food service personnel toward food allergies and Celiac disease” [PLoS One](#). 2018; 13(9)



Restaurants and Similar Retail Food Establishments Rule,”¹² we encourage FDA to require allergen disclosure on menus.

Conclusion

Thank you very much for your attention to these issues impacting the food allergy community. As detailed above, several highly feasible changes in public policy could make an enormous difference in protecting the health and safety of people experiencing food allergies and other related conditions. We look forward to working together on these important issues.

Sincerely,

Kenneth Mendez
President and Chief Executive Officer
Asthma and Allergy Foundation of America

¹² Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 FR 71155 (December 1, 2014).

ATTACHMENT

Constituent Comments in Support of the Medical Nutrition Equity Act (S.2013/H.R. 3783) and other Food Allergy Policy Priorities

1. Dear President Biden,

Hello, my name is [J.K.] mother of [B.] from New Hampshire Dover and I am writing to tell you why medical foods are critical in my life. My son 3.5 years old [B.] has multiple food allergies (peanuts, tree nuts, soy, eggs and sesame). Every day is a challenge to find safe food for him. We carry for him his EpiPen every day and everywhere we go. We believe that we will outgrow of his food allergies but for now we need to be very careful.

Sincerely,

[J.K.]

2. Dear President Biden,

Hello, my name is [R.A.] from Ronkonkoma, NY and I am writing to tell you why medical foods are critical in my life. I have a son with life threatening food allergies to milk, peanuts, eggs, and sesame. From the time [J.] was born we suffered from many issues related to his allergies. He needed special formula as a baby. This was very expensive and I worry about families who would not be able to afford this or other special foods for their children. Jaxson's diet has been very costly to us over the years. Thank you for your time.

Sincerely,

[R.A.]

3. Dear President Biden,

Hello, my name is [C.B.], from NYC, NY, from and I am writing to tell you why medical foods are critical in my life. My son has multiple food allergies, he is allergic to wheat, dairy, tree nuts and peanuts. He is 10 now and feeding him has been a challenge. I have to cook for him all the time, because it is not safe to buy prepackaged food, there is too much cross contamination. So he eats fresh vegetables, fruits, meats and fish, I have to buy special pasta, and other special foods that are safe for him, even if he wants chicken nuggets, I have to buy a special brand or make it myself. You can only imagine the cost of our groceries. It would be important to understand what families like ours go through, and help us. Also, since I am writing, it would be helpful to have a law for all restaurants, like in Europe, to list in their menus all the ingredients of their dishes. Our



children are citizens like everyone else, and yet they cannot live a normal life. Thank you for your kind attention.

Sincerely,

[C.B.]

4. Dear President Biden,

Hello, my name is [A.L.] from Kansas, Olathe and I am writing to tell you why medical foods are critical in my life. My first son was born in 2016. After weeks of profuse vomiting, he was hospitalized. I was informed he had a non-IgE allergy to milk and soy. We were breastfeeding and proteins were passing through my milk. I learned I would need to cut the foods from my diet. I opted to have him on Elecare at \$60 a can. He ate roughly 4 cans a week. That's nearly \$1000 a month since insurance wouldn't cover it. As a school teacher, we couldn't afford that. I chose the elimination diet instead since it was the only financial way to feed my child. My third born had much more significant reactions. He has hives, skins rashes, diarrhea and vomiting. He struggles to gain weight and is very small for his age. He has motor delays due to his lack of nutrition. He was diagnosed with FPIES at 11 months. Since I knew the formula costs from my first, I was again relying on an elimination diet to feed my child through breastfeeding. At 19 months, it was recommended that he move to supplemental toddler formula to increase his calorie intake. The only brand that met his medical needs was Kate Farms. Again, insurance refused to cover the formula. These are kids and their development suffers when they don't have access to the formula they need to grow and sustain life. Please stop allowing insurance companies to discriminate against my child because he is able to mouth feed instead of tube fed. I welcome any conversations you would like to have to learn more about the REAL lives this affects.

Sincerely,

[A.L.]

5. Dear President Biden,

Hello, my name is [L.W.] from Muskogee, Oklahoma and I am writing to tell you why medical foods are critical in my 11 year old son's life. He has asthma and two weeks ago was diagnosed with Alpha Gal Syndrome (AGS). This has completely changed the way we eat every meal. He is now allergic to mammalian meat, cow's milk & gelatin products. We learned how to read labels and quickly learned that not all ingredients are listed as they should be. AGS is life threatening to many children. Very few know what AGS is including medical staff and schools. Do you have any idea how many items have beef, pork, milk, and gelatin in them? This limits what they are able to eat drastically. He is now only able to eat chicken, turkey, fish and eggs. He plays football and I worry about his nutrition. We do not eat out anymore because restaurants use lard to fry food in and so many restaurants soak their food in beef broth to increase the flavor. We also risk cross contamination if they are using the same grill to cook beef or pork. There are even medications



and vaccines that are made with bovine or gelatin ingredients. Please, we need help in this epidemic crisis. Anaphylaxis is real and can be fatal.

Sincerely,

[L.W.]

6. Dear President Biden,

Hello, my name is [H.L.] from Austin, TX and I am writing to tell you why medical foods are critical in my daughter's life. My daughter was diagnosed with ARFID (avoidant restrictive, food intake disorder) due to a sudden anaphylactic experience with food allergies at the age of 10. Food started attacking her and as a result of her anxiety and true fear that food would kill her, she stopped eating. As a result, my daughter spent 9 months in and out of the hospital and eating disorder facility to help go through PTSD therapy and to learn how to eat again. The ONLY formula that she could have in her feeding tube was Neocate due to her multiple food allergies. Neocate is extremely expensive and difficult to get. Thankfully insurance covered the majority of cost while she was in treatment, however when she came home and needed the Neocate Splash supplement to maintain her body weight while she still fights with food variety, we are required to pay out of pocket and flavors are difficult to gain access to. It is imperative that medical foods be readily available to help kids and families have affordable access as needed to survive.

Sincerely,

[H.L.]