

Voice of the Patient Report: Food Allergies

Externally-Led Patient-Focused Drug Development Meeting

Public Meeting: September 9, 2021

Report Date: September 30, 2022



Submitted as patient experience data for
consideration pursuant to section 569C of the
Federal Food, Drug and Cosmetic Act to:

Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
U. S. Food and Drug Administration (FDA)

Hosted by the Food Allergy Collaborative



Food
Allergy
Collaborative



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Voice of the Patient Report: Food Allergies



This report is a summary by members of the Food Allergy Collaborative of an Externally-Led Patient-Focused Drug Development meeting held in-person and via livestream on September 9, 2021, in Bethesda, Maryland. It reflects the perspectives of patients and caregivers who participated in the public meeting.

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A Message of Thanks

Food allergies can wreak physical, emotional, and economic havoc for 32 million Americans of all ages, a number that continues to grow. For some, food allergic reactions are life-threatening.

The voices of those with food allergies and their caregivers must be heard and inform critically needed innovative new approaches to diagnose and treat food allergy. Elevating the patient and caregiver voices is central to the work and advocacy of the Food Allergy Collaborative, an alliance of non-profit organizations dedicated to improving the lives of those living with food allergies, and to industry partners.

On September 9, 2021, patients with food allergies and caregivers came together with advocates, health care providers, industry representatives and government officials for an Externally-Led Patient-Focused Drug Development (EL-PFDD) meeting. The meeting was organized into two overarching topics. The morning session explored the experiences of living with food allergies and the impacts on daily life. The afternoon session heard patient and caregiver views on different treatment approaches for individuals living with food allergies, both current treatments and desired new treatment options.

We would like to express our deep gratitude to everyone who joined us virtually and in person for this important meeting, starting with the patients and caregivers for sharing their invaluable lived experiences with food allergies.


Thank you to the Food and Drug Administration (FDA) for honoring our request to conduct this meeting and to all the FDA officials who participated. We offer a special thanks to Ronald Rabin, MD, Chief, Laboratory of Immunobiochemistry Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluations and Research for his contributions.

We also thank the generous supporters who financially sponsored this meeting: Genentech, DBV Technologies, Aimmune, and Novartis.

Linda Herbert, PhD, Assistant Professor in the Division of Psychology and Behavioral Health at Children’s National Hospital, provided a clinical overview of food allergies and treatment options. Session summaries were given by Eleanor Garrow-Holding, President and Chief Executive Officer of Food Allergy & Anaphylaxis Connection Team (FAACT) and Tonya Winders, President and Chief Executive Officer of Allergy & Asthma Network (AAN). We were privileged to hear stirring closing remarks from Kenny Mendez, President and Chief Executive Officer of the Asthma and Allergy Foundation of America (AAFA).

We are grateful to our industry sponsors and planning committee, who made this meeting possible, and to Larry Bauer and James Valentine of Hyman, Phelps & McNamara, PC, for their vital input into the meeting design and facilitation of the panel discussions.

We are pleased to be able to share the experiences and perspectives gathered at this meeting through this Voice of the Patient report. We believe these insights will inform future development of therapeutics and policies that improve the lives of patients living with food allergies.


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Executive Summary

Food allergies affect a growing number of Americans – currently more than 32 million – with potentially severe, constant, disruptive, and often life-threatening consequences.

Testimonials and comments shared by people living with food allergy and caregivers at the September 9, 2021 Externally-Led Patient-Focused Drug Development (EL-PFDD) meeting described the pervasive toll of food allergies on them physically, emotionally, socially, and economically. The comments showed the challenges and shortcomings of current diagnosis, prevention, and treatment options, highlighting significant unmet needs that must be addressed.

This EL-PFDD meeting, which marked the 50th EL-PFDD session held by the FDA, featured patient and caregiver testimonials, comments, and discussions in two sessions. The morning session centered on living with food allergies and the impacts on daily life, while the afternoon session was devoted to different treatment approaches for individuals living with food allergies, including current treatments and desired new treatment options.

Challenges of Living with Food Allergy and Impacts on Daily Life

Food allergy is an adverse health effect that arises from a specific immune response that occurs on exposure to a given food. Allergic reactions can involve many organ systems, including skin and mucous membranes, the gastrointestinal tract, the respiratory system, and the cardiovascular system. Food allergy can result in anaphylaxis, a severe allergic reaction that can have serious consequences, including shock and potentially death.

Patients and family caregivers described the imperative for constant vigilance to prevent exposure to something that would cause a reaction. They talked about the challenges of educating others about food allergy and the stigmatization that they sometimes felt. In addition, they spoke of anxiety, anger, and being overwhelmed – and how fear of exposure caused them to limit participation in social engagements, events, or going out to eat in public settings.

In addition, comments at the meeting showed how the challenges of living with food allergy are compounded for individuals or families who are low-income. Certain racial and ethnic groups, such as Black and Latino populations, also disproportionately experience challenges related to food allergy.

Need for New and Less-Invasive Treatments

Patients with food allergies and their caregivers described shortcomings and frustrations with current diagnostic methods and treatment options.

The diagnostic process for food allergy can be challenging. It is common for individuals to be misdiagnosed, under-diagnosed, or over-diagnosed – all of which burden the patient and their families unnecessarily. Patients and caregivers want accurate, less-invasive diagnostics that offer detailed information about their allergy. The primary strategy for managing food allergy is allergen avoidance, which is complex, anxiety-producing, and sometimes unattainable. Allergen avoidance can be especially difficult for those who experience food insecurity.

Treatment options are severely limited and can be challenging to administer, and at the time of this EL-PFDD meeting in September 2021, only one therapy has been approved to reduce food allergy; it is peanut-specific and limited to children and teenagers ages 4-17.

Patients and caregivers called for better, clearer, and more-consistent food labeling; explained the imperative for new, less-invasive diagnostic and treatment options; and urged development of new alternatives to an auto-injector to deliver epinephrine. Meeting participants also said that food should be considered a medical necessity, since food avoidance is currently the standard of care for food allergy and a necessary part of approved treatment options.

This EL-PFDD meeting was a critical step forward for the food allergy community. The insights and perspectives of people living with food allergy, which are collected in this Voice of the Patient report, can help guide the Food and Drug Administration (FDA) in partnership with pharmaceutical companies to develop the critical therapies that are desperately needed by this community.



Introduction: The Value of the Patient Perspective

Patient-focused drug development (PFDD) is a systematic approach to ensure that patients' experiences, perspectives, needs, and priorities are captured and meaningfully incorporated into drug development and education.

On September 9, 2021, the Food Allergy Collaborative hosted an Externally-Led PFDD (EL-PFDD) meeting focused on food allergies. The primary goal of this meeting was to provide researchers, drug developers, and the FDA with a robust understanding of patients' and caregivers' experiences with food allergies, including the physical, mental, and emotional toll living with food allergies takes on their quality of life.

Another goal was to collect key insights on current and future prevention and treatments from individuals affected by food allergies and their caregivers so outcomes of potential therapeutics can be measured in ways that are both clinically sound and therapeutically impactful.

Dr. Ronald Rabin, MD, Chief, Laboratory of Immunobiochemistry Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluations and Research, provided background on PFDD for participants. He noted the importance of this patient perspective to help the FDA understand the context in which regulatory decisions are made for new drugs.

Throughout the meeting, the voice of the patient was heard through courageous patient and caregiver testimonies, open discussions with the meeting attendees, live polling of the broader audience, and post-meeting commentary. Collecting these patient and caregiver insights is critical to the development of future patient-focused treatments and prevention strategies.



Overview of Food Allergies and Treatment Options

Food allergy is an adverse health effect that arises from a specific immune response that occurs reproducibly on exposure to a given food. Allergic reactions can involve many organ systems, including skin and mucous membranes, the gastrointestinal tract, the respiratory system, and the cardiovascular system. Reactions can range in severity. A severe allergic reaction called anaphylaxis can have serious consequences, including shock and potentially death.

In addition to learning how to avoid food allergens and communicate with others about food allergen avoidance, patients and their caregivers must learn how to recognize and treat anaphylaxis and how to educate others on that treatment. The extra time and intensive planning needed to manage food allergy can take a toll – on patients, caregivers, families, and communities. Psychosocial research indicates that affected children, their parents, and affected adults are reporting increased stress and anxiety related to the daily burden of managing food allergy. These can lead to a decreased quality of life, especially in social activities and diet diversity.

A clinical overview of food allergies and treatment options was provided at the meeting by Linda Herbert, PhD, Assistant Professor in the Division of Psychology and Behavioral Health at Children's National Hospital. Key points are highlighted below.

Prevalence and Demographics

- About 8% of children and about 11% of adults in the United States are diagnosed with food allergy, based on recent epidemiological studies¹. This can be diagnosed as early as infancy, as soon as a child ingests their first food, and all the way up through adulthood, sometimes to food they've eaten safely for years. In fact, nearly half of adults with food allergies developed at least one food allergy during adulthood.
- The top 9 most common foods that people have allergies to include peanut, tree nut, cow's milk, egg, wheat, soy, crustacean shellfish, fish, and sesame. These are the only food allergens that are required to be listed on food labels in the United States. Many individuals who are diagnosed with food allergy also present and manage comorbid conditions such as atopic dermatitis, asthma, and environmental allergies.
- A growing trend of data indicates a disproportionate impact of food allergy, as Black and Hispanic children are being diagnosed with allergies more frequently than their white counterparts. Asian and Black children are more likely than white children to have multiple food allergies. Additionally, families with lower incomes tend to spend more on emergency care than families with higher incomes.



Diagnosis

- The current process to diagnose a food allergy or allergies is not simple or quick. Typically, the individual or caregiver is asked by an allergist to provide a detailed food history of all the foods the individual has been eating and if the individual has had any symptoms after ingestion that are reproducible. Based on that history, the allergist will likely recommend skin prick tests, which look at the sensitivity of the skin to specific allergen extracts. From there, the allergist is likely to recommend specific blood tests to look at IgE antibodies for specific foods. This process can often take weeks to complete, and sIgE tests skin prick tests are not always reliable.
- As a next step, the allergist may also recommend an oral food challenge (OFC), which is the current gold standard in food allergy diagnosis. This procedure involves a step-wise ingestion by the individual of the allergen to determine the outcome. If the individual is able to tolerate the specific food during the food challenge, they then are able to go home and introduce that food into their diet.

Management and Treatment

- An elimination diet is the primary form of food allergy management, that requires the caregiver or patient to strictly eliminate the allergen or allergens from the patient's diet in order to keep the patient safe and to avoid allergic reaction.
- Elimination diets require patients and caregivers to be thoroughly informed and constantly vigilant. They must learn how to read food labels and communicate to others about the need to avoid certain food allergens. They must learn about cross contact, which is when a food that is not an allergen might be touched by a food that is an allergen, which then can make that first food unsafe. Patients and caregivers also must help educate all the institutions and individuals with whom the patient comes in contact – including educators, day care providers, friends, family members, and co-workers – in order to help keep themselves or the patients they care for safe.
- The only treatment available at the time of the meeting in September 2021 was Palforzia, an oral immunotherapy approved by the FDA in 2020 that is approved only for use among children ages 4-17 with peanut allergy.
- The only available option for treatment for allergic reactions and anaphylaxis is epinephrine administered intramuscularly.

¹ Gupta et al. Prevalence and severity of food allergies among US adults. *JAMA Network Open* 2019; 2(1):e185630; Gupta et al. The public health impact of parent-reported childhood food allergies in the United States. *Pediatrics* 2018; 142(6):e20181235; Mahadavinia et al. Racial differences in food allergy phenotype and health care utilization among US children. *J Allergy Clin Immunol Pract.* 2017;5:P352-357.E1.

Discussion Topic 1: Living with Food Allergy - Symptoms and Daily Impacts

The first session centered on the experiences of patients living with food allergy and the effects on their day-to-day lives. The session opened with a panel of five people who described living with food allergy or being a caregiver for a child with food allergies. Two panelists were patients, one was both a patient and caregiver of children with food allergies, and two were parents of children with food allergies who described the impact on the entire family.

Patients, caregivers, and others added their own perspectives and experiences during the moderated audience discussion during Session 1 and the 30-day comment period following the meeting.

Symptoms and health effects related to food allergy

Food allergies can produce a variety of symptoms. Patients and caregivers at the meeting described hives, difficulty with swallowing and breathing, nausea and vomiting, and anaphylaxis as common symptoms. The reactions can be severe, as one call-in participant, who has food allergies himself, spoke of losing a food-allergic child due to anaphylaxis.

In polling, meeting participants were asked to select the top three most troublesome food allergy reaction symptoms the patient or loved one had. The answers varied widely, with the three most-frequently listed symptoms in the responses being difficulty swallowing or throat tightening (18%); chest tightening, trouble breathing, or wheezing (17%); and hives, rash or itching (14%).

In one example, a patient panelist spoke about his symptoms after ingesting a food containing an allergen. At first his arm began to itch, then his chest, followed by an itch in his throat and a feeling that it was about to become more difficult to breathe. His teacher quickly took him to the school nurse, who administered an epinephrine auto-injector and called 911. He was wheeled out of the school and taken by ambulance to the hospital, an event that children in the school talked about for the rest of the year. The patient described how experiences like this can be traumatizing for young kids.

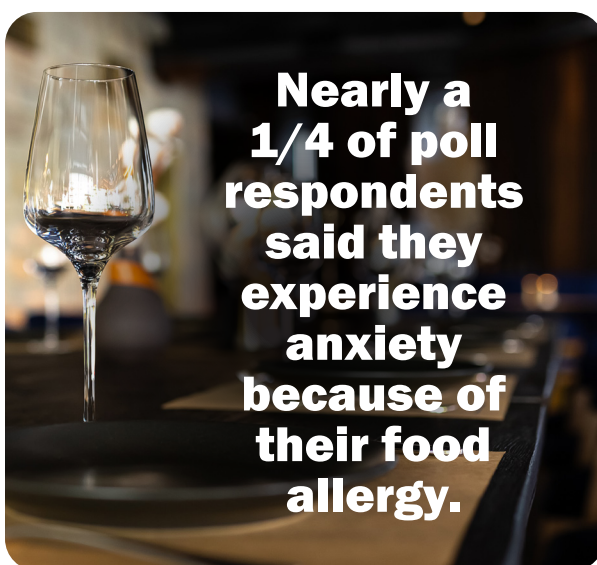
A mother described her child with a milk allergy as having a reaction where the baby was turning blue, causing them to rush to the doctor's office where the baby received epinephrine.

Another person described how a kiss from her husband, who had just eaten salmon, caused her face to tingle and swell.

Daily impacts of living with food allergy

Patients and caregivers described the imperative for constant vigilance to prevent exposure to something that would cause a reaction and the challenges of educating others about food allergy. They also spoke of high levels of anxiety and the stigmatization that they sometimes felt.

Polling results for participants in the first session showed that people with food allergy most frequently reported experiencing anxiety, anger/frustration, feeling overwhelmed, and loneliness. Helplessness, depression, and bullying were also experiences listed. Another polling question for participants asked what important activities they were unable to do or struggle with due to food allergies, and the top responses were participating in social engagements/events (25% of responses) and going out to eat in public settings (25%).



When asked through a live polling feature to select the top three things that worried participants the most about their loved one's food allergy, risk of accidental exposure was the most frequent response (30%). Other frequently cited worries were ability to access safe food/avoiding one's allergens (17%), mental health issues due to food allergy (11%), and more limited social engagements (10%).

Here are key points made by speakers and other participants:

- **Separation/Stigmatization** – One panelist spoke of how his elementary school forced all children with allergies to sit at lunch at the end of a table; no one wanted to be there and he described it as “very ostracizing.” In middle school, the patient had more friends and people who understood food allergy, but also faced bullying and threats to deliberately make him sick. This constant fear and an ongoing mistrust of whether food was really safe made social activities, school trips, and parties difficult and stressful.
- **Persistent anxiety about an allergic reaction** – A mother of a 12-year-old daughter with allergies to nine foods spoke about the impacts on the entire family. She described a trip where they experienced hours of delays for what should have been a two-hour flight. These delays had the family stressed and scrambling for something safe to eat, as when they finally arrived at their destination, all the restaurants and stores they had carefully researched earlier were closed. “The feeling of defeat consumed me and I could see it on my daughter's face. It's that all too familiar feeling of deflation. You just never get used to it,” she said. Notably, the mother said that her daughter was not attending the Food Allergy EL-PFDD meeting because of all the anxieties about traveling with a child with food allergies.
- **Overwhelmed by fear** – One panelist spoke about her experiences developing food allergies as an adult as well as having two children with food allergies. She described having her first anaphylactic reaction to food that she had eaten her entire life at 30 years old, just a few months after giving birth to her first child. This initial allergic reaction came as she was already a tired, overwhelmed, first-time breastfeeding mom, and she became terrified to eat for fear of having another reaction. The mother's anxieties escalated when she later began introducing her daughter to solid foods, and

her daughter had a severe reaction to hummus and was diagnosed with allergies to sesame and garlic. “I felt as though I was living life on a minefield and at any given time, I could have a misstep that would be the end,” she said.

- **Worries as a child grows older and becomes more independent** – A mother of two daughters with food allergies described the family's food allergy journey, starting with discovery of the allergies when the children had severe reactions as babies. She talked about her fears and anxieties after learning that, even as a loving mom, she could possibly make life-threatening mistakes. As a result, this mother said she was constantly vigilant, staying at every soccer practice; gymnastics workout; and ballet, choir and drama performance to make sure she would recognize an allergic reaction. The mother described how the daughter lost her set of epinephrine autoinjectors while on a class trip to China, but a teacher had an extra set. The mother worries as her daughter progresses through high school and prepares to move eventually out of their home. “When she launches from our house, I want her to be safe in the world, wherever she chooses to be in the world.”



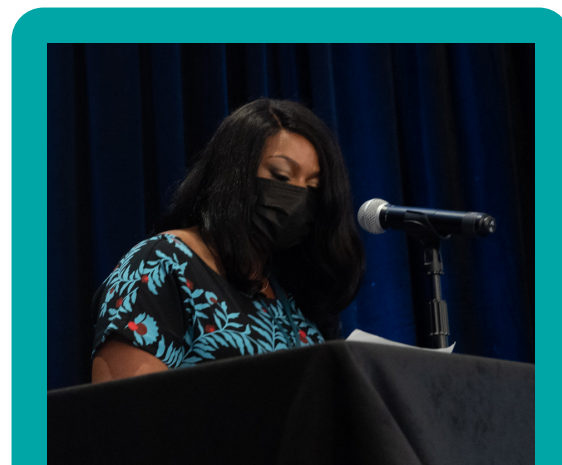
“As a baby [my daughter] showed hives and vomiting pretty consistently for peas, green peas and then for lentils. Her primary tells are definitely hives first. She has an itchy throat. Now as a six-year-old, she can talk about it, so she says her throat is spicy.”

– Jen, Caregiver



“There's a persistent anxiety that people with food allergy experience. You can have one great plan for the day and end up spending most of it in the emergency room.”

– Justin, patient



“You just never get used to it. We are exhausted and it feels as though there is no end in sight. We work to mitigate risk each day, but the anxieties are always there. They never go away.”

– Kaye, caregiver

The following is a sampling of insightful comments made by participants during the moderated audience discussion during Session 1 and from the 30-day open comment period following the meeting.

Importance of self-advocacy and educating others

- “Being a college student, some of the biggest things are making new friends and going out to eat with those friends and that’s obviously really hard. I’ve become known in a lot of my friend groups as the one with the peanut allergy...when you introduce yourself, you have to introduce your food allergy as well, because it’s a big part of your life.”
- “What has the greatest impact on our quality of life is the amount of planning that needs to go into everything for our two sons. The concept of carefree doesn’t exist with food allergies.”
- “As an adult who lives with food allergies, it’s been wonderful to be my own advocate, but one of the frustrating things that also means is that you necessarily have to invite other people into your experience and your disability and your chronic disease. I struggle to name another disease or another situation where other people necessarily have to be invited into that experience to protect you.”

Activities that are unfeasible or difficult because of food allergies

- “As an adult living with food allergies, one of the things I’ve really had to think about is traveling by myself and how do I do that safely? I’ve been places where I’ve made my own food and just thrown it in my bag. I try to focus on [the fact that] it’s not about the food as long as I have something to eat. It’s about the experience. And it’s taken me a while to get there.”
- “My four-year-old son has an egg allergy, and it has been limiting his ability and our ability to fully enjoy things like birthdays or eating out. Cupcakes, cakes and cookies are all things he cannot enjoy with his friends, and we struggle to feel comfortable and confident leaving our son in the care of others. The mental and emotional toll his allergy takes on us is way more significant than I anticipated.”
- “One of the things I remember from our allergist’s recommendation [when] we were talking about scouting,” said the mother of one panelist. “When [my son does] camping trips, what if one of the boys accidentally grabbed the cookware that we use and had some cross contact with that, what do we do? And what he said was, ‘You just don’t eat. Don’t take that risk.’ It’s much better to be hungry for that 24 hours than to risk having a reaction in the middle of nowhere.”

Mental and emotional impacts of food allergy

- “It’s just very hard. Do we trust the people that we bring our children to, whether it’s a family member, whether it’s a friend’s house, restaurant, play date, a playground, the school? How do you manage that without the mental anguish that we have on a daily basis?”
- “I have four kids that are anaphylactic to dairy, eggs, nuts, soy, fish, carrots, beans, on and on and on. During COVID, I’ve seen there’s pea protein in everything. So unfortunately, twice in a matter of two weeks, my youngest had to have six EpiPens, three back-to-back, overnight in the hospital, almost needed to be intubated, again, two weeks later, so he is a complete mess now. He won’t even have a glass of water without asking, ‘Is this okay for me to drink? Is this okay for me to drink?’ There are no ingredients on water. I see the anxiousness, which is awful.”
- “My daughter just turned 18 and she’s a new college student. She’s allergic to cow’s milk proteins and all of them, severely. And one of the most difficult things about her food allergy is at age 15, she was suicidal. As a parent, that’s very difficult to deal with. And through therapy and counseling, it was determined that her suicidal feelings were because of her food allergy anxiety and the way uncaring people treated her because of her food allergy.”



“I was afraid to eat anything outside of the house for fear that I would have a reaction. I was afraid to let my daughter participate in any event that had food for fear that she would have a reaction. I was afraid to live. I honestly couldn’t tell you how many life events we missed out on because of my fear, but I can tell you that it is not fun to be sitting on the sidelines, watching everyone else do life.”

– Lisa, patient and caregiver

Discussion Topic 2: Perspectives on Prevention and Treatments

The second session was focused on food allergy prevention and treatments. This afternoon session opened with a panel of three caregivers and two people living with food allergy.

Throughout this session, patients and caregivers spoke of the need for clearer and more consistent food labeling to enable them to better identify and avoid ingredients, as allergen avoidance is the only way to protect against a food allergy reaction. They urged that allergy-friendly food be considered medically necessary and covered by health insurance.

At the same time, participants spoke of the challenges of avoidance. One mother spoke of her son’s allergy to tree nuts and how people don’t quite understand that cross contact can occur no matter how many precautions are taken. She said: “People don’t think it’s serious. This is life and death when we ingest something; death can be in 30 minutes. And I don’t think food service staff understands that. I don’t think neighbors understand that. We’ve even had family members that kept forgetting my son had a tree nut allergy. Prevention and avoidance isn’t as easy as it sounds. We’ve tried that for decades, so that’s really difficult.”

In addition, several spoke of a need for new ways to deliver epinephrine, as fear of the needle in autoinjectors can be a barrier to deploying epinephrine. Overall, patients and caregivers called for new, less-invasive options to deliver epinephrine.

Polling of attendees during the meeting found that 61% of respondents said food avoidance was a strategy they used to address food allergy, with oral immunotherapy a distant second with 13% of responses. Oral immunotherapy (OIT) is a treatment option in which a food allergy patient eats increasing doses of their allergen to desensitize their immune system, training their immune system to not react to the problem food. OIT typically starts with very small doses of food allergen eaten under medical supervision. These doses are increased until a small, tolerated dose is reached that can be taken at home each day. OIT for peanut allergy, commercially known as Palforzia, is currently the only FDA-approved treatment option for food allergy and is only indicated for children between the ages of 4 – 17 years old. And even OIT does not allow patients to eat their allergen freely. Rather, it offers some protection in the event of an accidental ingestion of the allergen.

Patients, caregivers, and others added their own perspectives and experiences during the moderated audience discussion during Session 2 and the 30-day comment period following the meeting.

Burdens of food avoidance – costs and confusing labels

Panelists at the meeting described a range of burdens related to food avoidance. These included the time and effort required to review food labels to avoid accidental exposure as well as the burden of higher costs for food alternatives.

One caregiver talked of the struggle to manage the escalating cost of the family’s grocery bill with expensive alternatives, saying that “one of the greatest challenges has been the burden of food avoidance.” She noted that the dairy-free substitute that was most effective for her daughter cost more than \$15 a gallon, nearly four times the average cost of a gallon of milk in her city, and gluten-free flour cost over 1,000% more than all-purpose wheat flour. As a result, what had been weekly pancake breakfasts became treats only for holidays and birthdays. This family, which relied on the federal Special Supplemental Nutrition Program for Women, Infants and Children (WIC) and local food pantries, had difficulty finding safe food options.

One man who is both a patient and caregiver to a child with food allergies described the challenges of avoidance growing up in an impoverished area, where food scarcity was a major issue. He said his family didn’t know what safe foods were or what to avoid.



“Food avoidance has been financially challenging for our family. I’ve experienced this firsthand as a mother with limited resources dependent upon nutrition assistance programs.”

– Emily, caregiver

Another caregiver spoke of the challenges of trying to find and afford safe food options in the supermarket, and the continued concerns about the accuracy of food labels. She described how even with avoidance, her family is at the mercy of accurate labeling, saying that although her family was thrilled that sesame will be added as the ninth major allergen, it is vital that all ingredients are labeled to make safe decisions. This caregiver noted that food avoidance comes with multiple setbacks that can lead to exclusion. She said her son is limited in being able to participate in regular activities, such as eating lunch with his friends at school, going to restaurants, and “just feeling like a normal kid.”

One other participant noted the ubiquitous nature of precautionary allergen labeling, which is not regulated by the FDA, noting that, “nearly all commercial products have some sort of precautionary allergen labeling, and it’s near impossible to find anything without it.” He also spoke to the need for clearer, consistent precautionary allergen labeling practices that could help consumers better understand what is in food products to prevent anaphylaxis due to accidental ingestion.

A caregiver to a daughter with food allergies spoke of the challenges for parents or people with food allergies because the symptoms can be vague, noting that children vomit and children get hives, but that these are not always related to what they’re eating. What’s more, she said those vague symptoms have been complicated by inconsistency in food labeling, making it more difficult to determine what is causing the reaction.

New and better ways to diagnose food allergy

Meeting participants described the need for new ways to diagnose food allergies as well as the importance of more-accurate diagnostics. Overdiagnosis and inaccurate diagnosis are emotionally and financially burdensome. In addition, some diagnostic tests, such as skin prick tests and sIgE blood tests, have been found to have false positive rates of 50-60%.

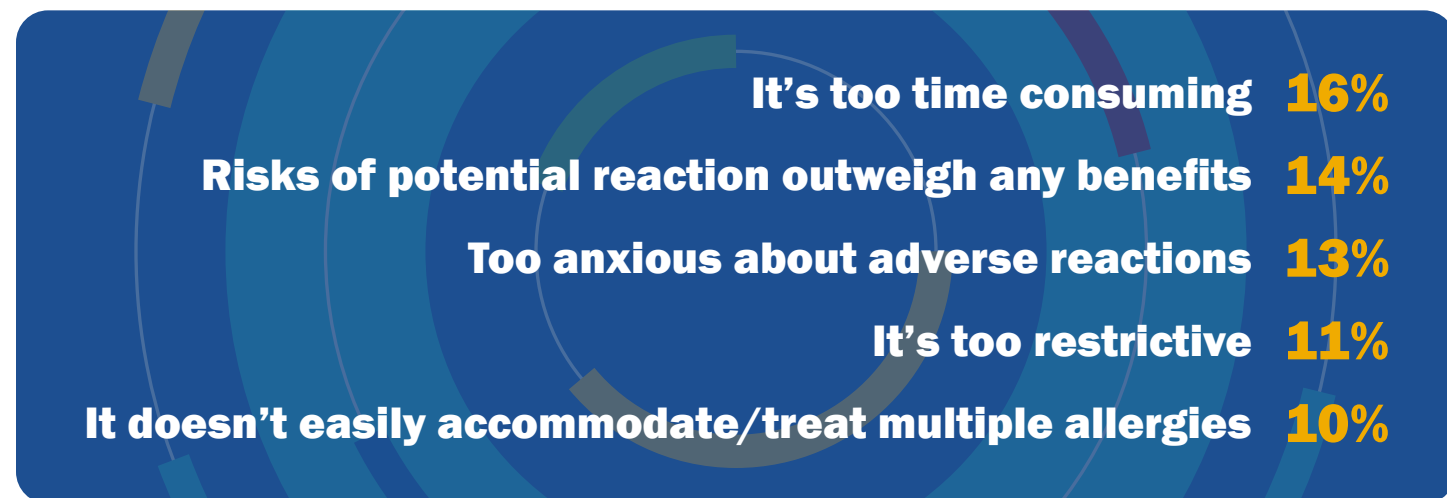
One caregiver described one such diagnostic test - the oral food challenge - as cumbersome, with the test taking a long time and requiring constant calming of her active toddler. In addition, her son already had developed some taste and texture aversions that made ingestion an exhausting psychological battle. Now age 16, her son is reluctant to do another food challenge. “The idea of consuming a food he has been told to avoid for fear of life-threatening anaphylaxis is unsurprisingly unappealing to him and incredibly anxiety producing,” his mother said.

Hesitancy/concerns about food allergy treatments

Patients and caregivers described their hesitancy and concerns about undertaking food allergy treatments.

A patient shared an ongoing internal debate of whether or not to pursue treatment: “I have not had a reaction since I was very little when I was first diagnosed, and that’s all because of food avoidance. I still have a lot of anxiety surrounding my allergy despite not having a reaction for so many years, but there’s this constant battle in my mind between should I pursue treatment? I’m at an older age now where it’s probably not offered for me. It’s been a battle even through adolescence of whether or not my mental health could take it as well as my physical health.”

Online polling during the meeting asked participants to indicate reasons that make them hesitant to undergo current or future food allergy treatments. When presented with an extensive list of possible reasons for hesitancy, the top five responses were:



Desires for more treatment options

Speakers and participants in the meeting were eager to see more research and options for effective food allergy treatments. This is of high importance to food allergic patients as there is currently only one FDA-approved treatment for food allergy: oral-immunotherapy for peanut desensitization in children. One patient testified about the need for more treatment options regardless of age and lifestyle to lessen the propensity for accidental reactions.

Polling of participants during the meeting found that eating the allergen without any restriction was the most commonly selected response, selected as a top two in more than a third (35%) of responses. In addition, 22% said they wanted a future treatment to provide “bite protection,” meaning there would be a lower chance of having an allergic reaction if a small amount of the food allergen is ingested.

One caregiver commented that current therapies are heavily based in the prevention and reversal of symptoms in young patients. Her son was nearing his 17th birthday, and she said that he is also nearing the end of a window for effective treatment, as Palforzia is approved only for children ages 4-17. She said that without treatment, her son’s “age turns his food allergies into a life sentence.”

Another caregiver said that patients need lasting therapeutics that go beyond the existing treatment for peanut allergy and are inclusive of those with other atopic conditions. Her son didn’t qualify for desensitization clinical trials due to his asthma, a common comorbid condition that can fatally complicate an allergic reaction. However, he began having difficulty swallowing while waiting for clinical trials to be inclusive of those with asthma. After several invasive endoscopies, along with elimination diets, he was diagnosed with eosinophilic esophagitis, (EoE) a second disqualification from most therapies.

Other comments about treatment and management strategies included:

- “The milk patch has opened up exciting opportunities for us. My son went from being severely allergic to milk, to now being able to continue to desensitize him to the milk protein with oral immunotherapy. Without the patch, he would not have been eligible for OIT. He is now drinking 4 ounces of milk each day. The patch was literally a life saver. It was very easy to use and was a great experience. We consider ourselves to be so fortunate, because now we don’t have to worry that he might die from anaphylaxis if there is a small amount of cross contamination.”
- “[My] son was one of the first participants in the CoFAR6 study out at Mount Sinai in New York City. The only side effect [my son] experienced was minor skin irritation at the patch site, which decreased over time. I am aware that the patch isn’t a cure. [My son] will continue to avoid peanut products and is still mindful about accepting food that could be unsafe. We think of life as ‘BP’ and ‘AP’ - before and after the peanut patch. Our quality of life has improved so much. This is an option all families who have a child with peanut allergy deserve to have as an FDA-approved treatment.”

Concerns about food allergy treatment, seeking better treatment options

- “I am a mother of a 13-year-old son who was diagnosed at 6 months old with allergies to peanuts, all shellfish, all tree nuts, egg, milk, wheat, potatoes, and strawberries. We live in a rural area in north Mississippi about 20 minutes from Tupelo. Over the next 10 years the closest trial location I could find was in Little Rock, Arkansas, over a seven-hour round trip for us. Fast forward to 2019, I learned of a trial with a location in Birmingham, Alabama, which is only a five-hour round trip for us. We began the qualification and enrollment process in October 2019. Aside from the basic cost of time and travel related to participating in the trial, given the distance we had to travel and the fact that there was very little emergency care on our routes to home after food challenges, we also had that expense of hotel rooms. Our trial experience not only showed the need for better diagnostics, given the numeracy to oral food challenges that he underwent. It also showed a need for better access for families in rural areas to treatment and to trials - and also more robust financial support for families participating in trials.”



“The food allergy community needs three things right now: accurate and definitive diagnostic tools; accessible therapies with lasting results; and less invasive emergency medicine to combat anaphylaxis.”

– Erin, caregiver

- “I have eight-year-old twin boys. One of my sons is very allergic; he has five significant food allergies and asthma on top of that, and it was life changing. We knew there was a chance of getting him into a clinical trial. It’s time consuming, yes. The scariest part for us in enrolling my son in the clinical trial was when you’re signing to say, ‘Hey, it’s worth the risk. We know things can happen, but it will be in a medical setting.’ And that was really hard for us, but it was the right decision. We would just ask that the FDA keep considering any advancement to help kids and people with food allergies, whether its novel EpiPen, or whether there’s other ways to help build up the body to reduce immune response.”
- “My daughter has been through a clinical trial for multi-allergen OIT with Xolair, and that was in 2014. She’s been in maintenance for seven years. And for us it has been a life-changing experience. Now she can pretty much eat at any restaurant. And she knows that if she accidentally has more of her allergen than she should, that she will be safe and that she will not have anaphylaxis. It has allowed her to travel internationally by herself or with her class, which I never dreamed would be possible before this treatment. I hope that the FDA will consider these innovative treatments that combine drugs such as Xolair, which is approved for asthma treatment, but has not yet been approved for food allergy treatment in combination to do multi-allergen OIT at the same time.”
- “I hope that for the FDA listening in today, that hearing people who have gone through OIT and have achieved the bite protection and what a life-changing moment that has been for them, I hope that really comes through about the challenges of dealing every day with a food allergy that it is life-changing to be able to have one bite.”

Seeking less-invasive alternatives to administer epinephrine and address anaphylaxis

Participants highlighted the need for affordable, easy-to-use emergency medication.

“I’d love to see EpiPen be available without a needle,” said one participant who has trained hundreds of lunch volunteers on how to use it. At the same time, she has never used an auto-injector herself, nor has her daughter who has a food allergy. The mother notes the hesitation and doubt on whether something is really an allergic reaction that requires use of epinephrine: “You’re in emergency mode, and there is a little bit of fear about using an auto-injector that has a needle.”

Audience polling during the meeting found that an overwhelming majority (88%) of respondents have an epinephrine auto-injector. The most common issue posed by carrying epinephrine auto-injectors cited was inconvenience or difficulty of carrying (37% of responses), followed by forgetting it (22%) and fear of using the auto-injector (17%).

One caregiver said that when her son suffered his first anaphylactic reaction to sesame, it required epinephrine and a visit to the emergency room. It led to many questions and feelings, especially regarding the epinephrine treatment. “What are the long-term effects? Will there be emotional effects from what my son saw as a larger-than-life needle penetrating his skin? And could there be an easier way? We hope to have comparable treatments to the EpiPen available that are far less scary for the recipient and less intimidating for those having to administer it,” she said.

Another caregiver recalled her hesitancy to use the auto-injector when her son began wheezing and feeling nauseous at a restaurant. She continued to look for skin symptoms to confirm he was experiencing anaphylaxis, which she later learned do not appear 10% of the time. As her son’s pallor turned an unnatural shade of blue, two neighbors who were doctors came over, but even they hesitated to use the auto-injector because of concerns over administration and elevated heart rate. The caregiver said, “If a well-informed food allergy parent could hesitate to use epinephrine when it was needed, anyone could. How could we expect our children and teachers, friends and caregivers to both recognize the symptoms of an allergic reaction and self-administer epinephrine when two doctors debated if it was needed?”



“Living with multiple allergies is stressful, but I’m hopeful. I ask the FDA to consider more research in allergy prevention and treatments that address the whole person and the relationship between food allergies and other allergic diseases.”

– Dawn G., patient

Other comments about carrying and administering epinephrine auto-injectors included:

- “My daughter has had multiple anaphylactic reactions. Some of them to her OIT doses, some of them to finding out new allergens. When she was four, we had to use epinephrine and the needle bent and got stuck in her leg. This was probably the first time that she would really remember that reaction and the treatment of that reaction. And the next time she needed an epinephrine she begged me not to give it to her and I obviously had to and did and now we’ve unfortunately experienced it so many times that I make her administer [it] for the practice, if needed, because of that fear. We’re afraid as parents to give it. And that is one of our biggest barriers in that treatment of epinephrine auto-injectors the way they currently exist.”
- “I know the most stressful and traumatizing part of this all is having to use an Epi-Pen, because it’s not simply just ‘using’ it,” said one caregiver who is living with food allergies and now raising a daughter with food allergy. During the most stressful couple of minutes, you then have to find someone to jab a needle into you. And as a child that is terrifying. I know there is a nasal spray in the works, but I have been hearing about it for years. What is being done to speed up that process?”
- “I have two daughters who have food allergies. One just finished college; one is starting college. And that one that’s in college currently is the most extreme...every type of nut, sesame, hummus. You name it, she’s allergic to it. She carries three [EpiPens] on her at all times. So, I think for her mentally it’s like a security blanket because she’s had those episodes where it’s just like each time it gets worse. So, she just wants to feel like in her own sense that she’s fully prepared.”
- “I’m the mom of a 16-year-old with peanut and tree [nut] allergies. [My daughter] has not anaphylaxed since she was 2 years old, so she honestly has zero memory of that moment and of that day. And what I have found is that the further we are away from that anaphylactic event, to be honest, the more cavalier we become. I know it’s probably not the safest thing, but it is the reality. [In regard to carrying auto-injectors] In [my daughter’s] case it’s the convenience, the cool factor, the not wanting people to know that she’s different. All of those psychosocial aspects of living with a food allergy. What other condition do you purchase a medication that you never have to use or hope you never have to use?”
- “It’s a bulky item. It requires them to maybe carry extra baggage or fanny packs or other items on them, which they may not already be used to carrying. I think a lot of people also forget that epinephrine is sensitive to temperature and so it doesn’t travel very well. It doesn’t do great in these hot summer months that we’ve had. It doesn’t do so great in the cold months; the injector itself, the mechanisms can misfire under those kinds of stringent conditions, even when the medication it holds is stable. So, it’s more complicated even than just the carrying part, which is super inconvenient.”
- “It simply makes everything more difficult. It means that when you have a day at the beach, you have to pack a cooler for your epinephrine, but it can’t be too cold, but it also can’t be too hot. If you’re hiking or skiing or sledding or just having a day outdoors, those cold temperatures could also be equally difficult and you have to figure out a way to manage that and keep it warm against your body, potentially. That also can be cumbersome and inhibit the way you move or the way you operate or the way you enjoy your outdoor activities.”



“Food allergies have permeated every element of the choices that I’ve

made, the person I’ve become, and the experiences that I hope to have. Viable treatment to minimize risk of exposure would change every facet of my life and has the potential to change a life-ending accident into an accident of mere discomfort.”

– Maeve, patient

Innovative solutions for food avoidance needed to address disparities on race and income

One parent called on the FDA to consider approving innovative solutions that solve for food avoidance, noting that without changes, wide disparities and food allergy outcomes based on race and income will continue. The parent spoke of going to a local food pantry, being in line for hours as others left with carts full of food. “By the time it was my turn to shop at the pantry, the only safe foods available were two potatoes and a jar of salsa.” She urged the FDA to take steps to ensure that all new approved drugs meet diversity standards and clinical trials, as food allergy has a significant burden in communities of color, yet new and emerging treatments continue to under-represent communities of color in clinical trials.

Other suggestions on treatments and research

Patients and caregivers offered several other suggestions for research and treatments, such as more research in allergy prevention and treatments that address the whole person; the relationship between food allergies and other allergic diseases; early intervention treatments; and translation of information on auto-injectors into different languages.

One patient described how eczema, hives, inflammation, and hay fever have always been part of her life, but how her allergies have changed over time. As she avoided and then reintroduced foods, some led to more-severe reactions than before. This patient also has a range of food sensitivities, which she acknowledges are different than allergies, but adds that they are significant to her because they affect her skin, weaken her immune system, and cause inflammation. This patient said an ideal treatment would address the food allergies, the environmental allergies, and her weakened immune system that contributes to the sensitivities and inflammation.

Other comments included:

- “I also hope for early intervention treatments that offer long-term tolerance without lifelong maintenance, as well as expanded treatment options for food allergies and more rapid approval for other top food allergens.”
- Support for Epicutaneous immunotherapy, (EPIT) which exposes tolerance-promoting immune cells in the skin to an adhesive dermal patch containing a small (micrograms) dose of food protein. EPIT starts with a small initial dose that is increased over time by wearing the patch for longer periods of the day, until a maintenance dose is reached in which each patch is worn 24 hours and replaced daily. Patches are currently being developed to treat peanut, milk and egg allergies. “EPIT is a valuable treatment option for patients with severe allergy or who are too sensitive to start OIT. It provides a platform to desensitize them without the use of adjuvant medications or injections. I hope the FDA will consider the use of EPIT as it has shown incredible results in individual patients and quality of life.”
- “I would like to see if they could have [ingredients] in other languages, even with the EpiPen. I have to search each word to see what it means. Is it suitable for my child? If it’s in other languages as well, it would help many different people, not just people who speak English, because we live in a society that is diverse.”



“My challenges as a caregiver revolve around the future. What is available and what planning is being put into place to seek a cure to this disabling disease? I would like to see additional treatments that go beyond peanut with less burden during therapy.”

– Priscilla, caregiver

CONCLUSION

The input received through the Externally-Led Patient-Focused Drug Development meeting on food allergies and the comments made later to the public docket underscored the severity of the disease and showed the daily impacts, concerns and anxieties for people with food allergies and for caregivers of children with these food allergies. The meeting highlighted the need for new treatment options and for new methods for delivering epinephrine without use of an auto-injector.

Patients and caregivers have a unique ability to contribute to the understanding of the FDA of the disease and its effects through their valuable insights on the disease, diagnosis and treatments. It is our hope that their input and insights can help inform new policies and development of safe and effective treatments for food allergies, ones that are clinically sound, therapeutically impactful, and meaningful to those whose daily lives are affected by food allergies.



Appendix I: Meeting Agenda & Discussion Questions

Externally-Led Patient-Focused Drug Development Meeting for Food Allergies

Thursday, September 9, 2021

Hyatt Bethesda

Agenda

10:00 - 10:05 am Welcome & Opening Remarks

Lisa Gable, FARE CEO

10:05 - 10:15 am FDA Remarks

Ronald Rabin, MD
Chief, Laboratory of Immunobiochemistry
Division of Bacterial, Parasitic and Allergenic Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
U. S. Food and Drug Administration

10:15 - 10:25 am Background on Food Allergies and Treatment Options

Linda Herbert, PhD
Assistant Professor in the Division of Psychology and Behavioral Health
Children's National Hospital

10:25 - 10:35 am Meeting Overview (Live, in-person)

James Valentine, Moderator
Associate, Hyman, Phelps, & McNamara PC

10:35 - 11:10 am Topic 1 Panel: Symptoms and Daily Impacts of Food Allergy

11:10 - 12:10 pm Large-Group Facilitated Discussion on Topic 1

Discussion questions:

1. What was your journey to food allergy diagnosis (length of time to diagnosis, misdiagnosis experience, barriers and burdens in the process, uncertainties?)
2. How does having a food allergy impact your daily life and mental health?
3. What are the biggest challenges of having a food allergy?
4. Let's talk specifically about adult-onset food allergy: What have been the specific challenges of developing food allergy in adulthood? How does this compare to those with childhood-onset food allergy?
5. How has having a food allergy affected the nutrition you are receiving from your food?
6. How has access to food allergy safe foods, or lack thereof, impacted your daily life?
7. How does having multiple allergies impact you?
8. How do you manage top nine allergies compared to non-top nine allergies? Are their complications that exist? Are there differences with peanut allergy compared with other top nine?

12:10 - 12:15 pm Morning Recap

Eleanor Garrow-Holding, FAACT President and CEO

12:15 - 1:15 pm Lunch

1:15 - 1:20 pm Afternoon Welcome

James Valentine

1:20 - 1:55 pm Topic 2 Panel: Patients' Perspectives on Prevention and Treatments for Food Allergy

1:55 - 2:55 pm Large-Group Facilitated Discussion on Topic 2

Discussion questions:

1. Are you currently undergoing treatment for your food allergy? Please share your experience.
2. For those who have undergone treatment: What are the most significant downsides to current treatment options, and how do they affect your daily life?
3. For those who have not undergone treatment: What challenges or barriers to treatment have you encountered?
4. What challenges or barriers to epinephrine access have you encountered?
5. As a parent, what strategies have you introduced to attempt to prevent your child from developing a food allergy?
6. Question for those with food allergy: What specific things would you look for in an ideal treatment for your food allergy? Logistics of the treatment but also the ultimate outcome desired?
7. Question for those with food allergy: What specific things would you look for in an ideal treatment for your food allergy? Logistics of the treatment but also the ultimate outcome desired?
8. Question for caregivers: How does this differ from what you are looking for in an ideal food allergy treatment and management strategy for your child?
9. What obstacles are you willing to endure during treatment?

2:55 - 3:00 pm Afternoon Recap

Tonya Winders, AAN CEO

3:00 - 3:10 pm Summary of Meeting

Larry Bauer, Facilitator
Senior Regulatory Drug Expert, Hyman, Phelps, & McNamara PC

3:10 - 3:15 pm Closing Remarks

Kenny Mendez, AAFA CEO

Appendix II: Meeting Panel Participants

Session 1 Panelists: Symptoms and Daily Impacts of Food Allergy

- Brandon W., Danville, KY, living with food allergies
- Justin Z., Chicago (now living in New York City), living with food allergies
- Dr. Kaye C., Charlotte, NC, parent of a child with food allergies
- Lisa R., Cherry Hill, NJ, living with food allergies and parent of children with food allergies
- Stephanie L., Mountain View, CA, parent of children with food allergies

Session 2 Panelists: Patients' Perspectives on Prevention and Treatments for Food Allergy

- Emily B., Kansas City, MO, parent of children with food allergies
- Erin M., McLean, VA, parent of a child with food allergies
- Maeve W., Columbus, OH, living with food allergies
- Priscilla H., Los Angeles, CA, parent children with food allergies
- Dawn G., Kansas City, MO living with food allergies

Appendix III: Project Team



Anita Roach, MS

Vice President of Community Programs & Education
Food Allergy Research and Education



Eleanor Garrow-Holding

President & Chief Executive Officer
Food Allergy & Anaphylaxis Connection Team



Elisa Zizza, MA

Manager of Corporate and Foundation Relations
Asthma and Allergy Foundation of America



Emily Brown

Founder and CEO Free From Market
Founder Food Equality Initiative



Erin Malawer

Executive Director
AllergyStrong



Erin Martinez, MS

Interim CEO
Food Equality Initiative



Hannah Jaffee, MS

Research Analyst
Asthma and Allergy Foundation of America



Jenna Yost, MS

Health Education Research Manager
Food Allergy Research and Education



Kelly Barta

State Advocacy Project Manager
Allergy & Asthma Network



Kenny Mendez, MBA

Chief Executive Officer & President
Asthma and Allergy Foundation of America



Thomas Silvera

Chief Executive Officer Elijah-Alavi Foundation
MSHS-PH

Appendix IV: Organization Descriptions



AllergyStrong
AllergyStrong is an organization dedicated to serving the food allergy community, with particular focus on the underserved population. AllergyStrong brings education, expertise and awareness directly to patient families and the community institutions that support them (schools, aftercare programs, places of work, community health programs, and others). By increasing access to medical care, prescription drugs and safe food as well as advocating for policies that protect all patients, AllergyStrong aims to improve quality of life for all who live with food allergies.



Allergy and Asthma Network (AAN)
The Allergy & Asthma Network is the leading nonprofit patient education and advocacy organization for people with asthma, allergies, and related conditions. The patient-centered network unites individuals, families, health care professionals, industry, and government decision makers to improve health and quality of life for Americans with asthma and allergies. The organization specializes in making accurate medical information relevant and understandable to all while promoting evidence-based standards of care.



Asthma and Allergy Foundation of America (AAFA)
Founded in 1953, AAFA is the oldest and largest non-profit patient organization dedicated to saving lives and reducing the burden of disease for people with asthma, allergies and related conditions through research, education, advocacy and support. AAFA offers extensive support for individuals and families affected by asthma and allergic diseases, such as food allergies and atopic dermatitis (eczema). Through its online patient support communities, network of local chapters and affiliated support groups, AAFA empowers patients and their families by providing practical, evidence-based information and community programs and services. AAFA is the only asthma and allergy patient advocacy group that is certified to meet the standards of excellence set by the National Health Council. For more information, visit www.aafa.org.



FAACT Food Allergy & Anaphylaxis Connection Team (FAACT)
FAACT's mission is to educate, advocate, and raise awareness for all individuals and families affected by food allergies and life-threatening anaphylaxis. Whether it's keeping children safe at school, responding to food allergy bullying, traveling, preparing for college, dealing with workplace issues, or simply taking the family out for dinner, FAACT has the facts you need to manage food allergies and stay healthy. FAACT is your voice for food allergy awareness.



Food Allergy Research and Education (FARE)
FARE enhances the lives of individuals with food allergies, empowering them to lead safe, productive lives with the respect of others through education and advocacy initiatives and improved awareness around healthcare options and treatment. FARE's mission is simple - Improving the life and health of the 32 million Americans with food allergies and providing hope for the promise of new treatments. FARE has turned over \$100 million in donor gifts into ground-breaking research and has provided a voice for the community, advocating on its behalf and offering hope for a better tomorrow.



Food Equality Initiative (FEI)
Since 2014, Food Equality Initiative has strived to make an impact on feeding the hungry, we are also making significant strides in increasing knowledge and raising awareness about nutrition security in those with diet-treated illnesses. We are a leader in supporting research and advocating for traditionally underrepresented populations in healthcare. To do our work, FEI collaborates with and receives funding from healthcare providers, local and national nonprofit organizations, government agencies, schools, food manufacturers, and generous individual donors. Food Equality Initiative fights for nutrition security and health equity for all.



Elijah-Alavi Foundation
The Elijah-Alavi Foundation was founded to ensure that all infants and children with severe food allergies and asthma have safe spaces to learn and socialize in daycare centers and schools. We intend to achieve this mission by partnering with a network of organizations and professionals to provide the training, resources, and counsel for educators and school administrators to implement policies that reduce the risk of life-threatening allergic reactions in children. The most imperative aspect of such a partnership is the shared interests in the diverse communities we serve, as every demographic represented among them depends upon us for our commitment to public health and overall well-being.

Appendix V: Incorporating Patient Input into a Benefit-Risk Assessment Framework for Food Allergy

Introduction

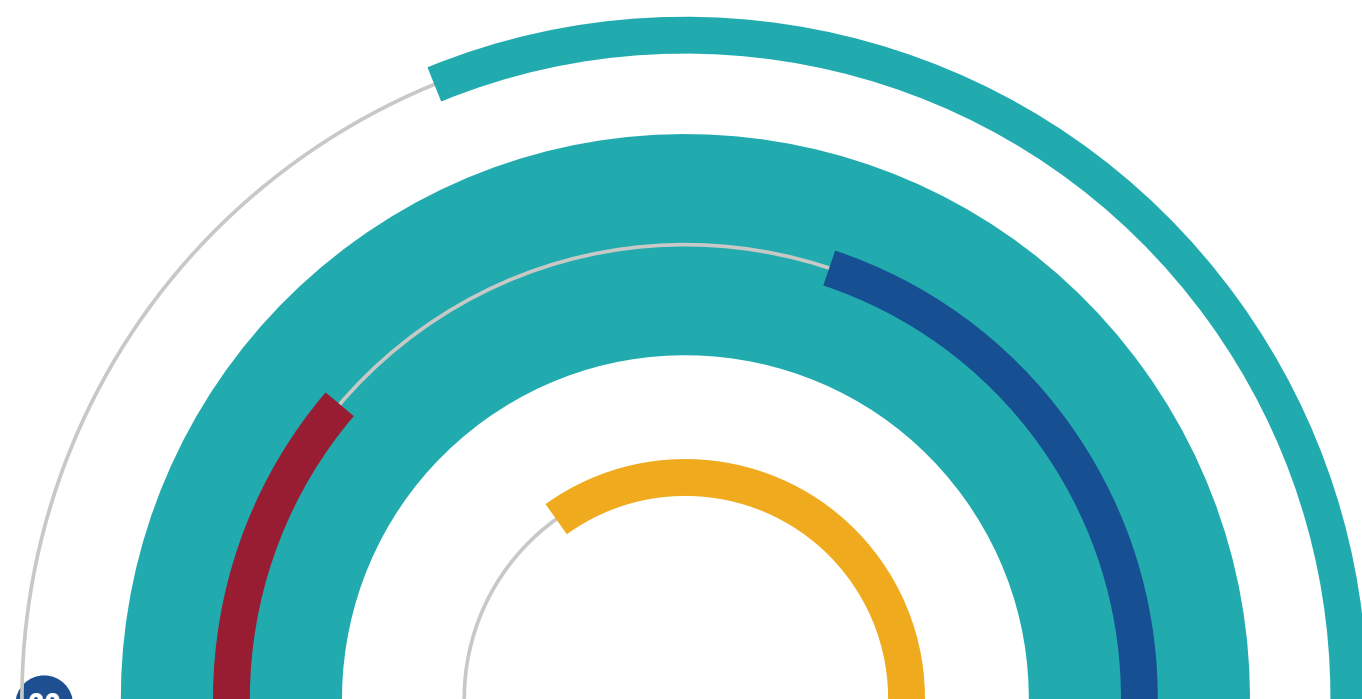
Over the past several years, FDA has developed an enhanced structured approach to benefit-risk assessment in regulatory decision-making for human drugs and biologics.⁸ The Benefit-Risk Assessment Framework involves assessing five key decision factors: Analysis of Condition, Current Treatment Options, Benefit, Risk, and Risk Management. When completed for a particular product, the Framework provides a succinct summary of each decision factor and explains FDA's rationale for its regulatory decision.

In the Framework, the Analysis of Condition and Current Treatment Options rows summarize and assess the severity of the condition and therapies available to treat the condition. The assessment provides an important context for drug regulatory decision-making, including valuable information for weighing the specific benefits and risks of a particular medical product under review.

The input provided by patients and patient representatives through the Patient-Focused Drug Development meeting for Food Allergy and docket comments will inform our understanding of the Analysis of Condition and Current Treatment Options for this disease.

The information in the top two rows of the sample framework for food allergy below draws from various sources, including what was discussed at the Patient-Focused Drug Development meeting held on September 9, 2021. This sample framework contains the kind of information that we anticipate could be included in a framework completed for a drug under review for food allergy. This information is likely to be added to or changed over time based on a further understanding of the condition or changes in the treatment armamentarium.

Commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V) include further development and implementation of the Framework into FDA's review process. Section 905 of the FDA Safety and Innovation Act also requires FDA to implement a structured benefit-risk framework in the new drug approval process. For more information on FDA's benefit-risk efforts, refer to <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.



Sample Benefit-Risk Framework for Food Allergy

Dimensions	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition	<ul style="list-style-type: none"> Food allergy is a disease that arises from a specific immune response that occurs reproducibly on exposure to a given food. Approximately 32 million individuals have food allergies in the U.S., about 8% of children and 11% of adults. Black and Hispanic children are being diagnosed with allergies more frequently than their white counterparts and Black children are 2 to 3 times more likely to suffer from fatal anaphylaxis than white children. Food allergic reactions can involve many organ systems, including skin and mucous membranes, the gastrointestinal tract, the respiratory system, and the cardiovascular system. Reactions range in severity; a severe allergic reaction called anaphylaxis can have serious consequences, including shock and potentially death. 	<ul style="list-style-type: none"> Food allergy is a potentially life-threatening disease affecting millions of Americans. The burden is exacerbated for low-income patients and patients of color and their families. Both adults and children living with food allergy experience significant physical, psychological, and social effects. Allergen avoidance inhibits diet diversity and results in anxiety around traveling and eating out. The fear and anxiety around food allergic reactions is a considerable detriment to patients' quality of life; it enhances a fear of eating and may result in poor nutrition or disordered eating. There is a need for measurement tools that accurately assess and improve quality of life for food-allergic patients.
Current Treatment Options	<ul style="list-style-type: none"> There is only one FDA-approved treatment for food allergy, Palforzia, an oral immunotherapy approved by the FDA in 2020 and only indicated for children ages 4-17 with peanut allergy. The most widely used management strategy for food allergy is allergen avoidance, which requires constant vigilance, educating others about cross-contact, and is made difficult by lack of clear precautionary allergen labeling. The only available option for treatment for food allergic reactions and anaphylaxis is epinephrine administered intramuscularly. A limited number of patients have undergone clinical trials for investigational methods to treat food allergy such as Sublingual Immunotherapy (SLIT) and Epicutaneous Immunotherapy (EPIT). 	<ul style="list-style-type: none"> Patients with food allergy have a significant unmet medical need for treatments. Patients and their caregivers are seeking less-invasive, more-inclusive treatment options, with treatments developed and approved for adults with food allergy and those other than peanut. The speed with which treatments are approved needs to be accelerated and the repurposing of existing treatments for conditions like asthma and eczema to treat food allergy should be considered. The invasiveness and fear of the needle in epinephrine autoinjectors, the only current treatment for anaphylaxis, presents significant risks to safe epinephrine administration and hesitancy in utilizing the life-saving medication. Patients emphasized the need for solutions to reduce or remove burdens with allergy avoidance.

Appendix VI: Full Patient and Caregiver Testimonies

Session 1 Panel Remarks: Symptoms and Daily Impacts of Food Allergy



Brandon W., Living with Food Allergies

My name is Brandon W. I am from Danville, Kentucky. I am 19 years old. I was diagnosed with egg and dairy allergy at the age of 13 months. I thankfully outgrew the dairy allergy rather quickly, but egg is one that has stuck around, and I would like to speak on how it was growing up through school. In elementary school it was an interesting time of little kids not knowing any better. And sometimes throwing food around would always give me anxiety or I'd worry what if one of these kids took something from my lunch box, and swapped it with his? Mildly unreasonable fears now that I'm older, but at the time, it was very serious. I was worried. And one of the solutions that the school implemented was sitting me with kids with other allergies at the end of a table. And I would always sit with them. But as time grew on, I realized that they didn't exactly enjoy me there, which felt not great. It was very ostracizing. But once I was out of elementary school and moved to middle school, things got better and worse. I had more friends. I had more people that were understanding, but the bullying about the allergy, the teasing, the questions, the threatening to get me sick was by far the most atrocious thing I've heard because they don't understand what that really means to someone

with a food allergy, that is beyond serious. And I have to explain that to them every time. And most of the reactions I get were disregard for my concern, and that hurt, that really hurt. The school offered to allow me to not bring my lunch and just make it safe for me, but considering the distrust I already had in my fellow students, and the inaction by the school to do anything when I brought it up, led me to not trust the kitchen staff as well. I didn't want to risk getting sick. That was my biggest fear was getting sick.

And the uncertainty of safe food, just not only by the school staff, but also from fellow parents, whether they brought cupcakes or cookies to any event or whether my friends said their mom had brought something. And even when they said their mom had made it safe, or made an effort, I couldn't trust them, which made me feel very bad because my friend went out of their way to tell their parents to make something safe for me. And I still didn't feel safe eating it because there's only a handful of people nowadays that I can trust to make food safe for me. And with this constant fear, and untrust of friends, it made social activities really hard. It made school trips very difficult, even just parties with friends was... It's always stressful. It's always, "What am I going to eat? How am I going to get food? What if I get sick?" What if I get sick is the first question in my mind at all times, no matter where I go.

And I remember that fear of getting sick and expressing that to some of my friends on a school team, whenever we went out to eat, it was always met with, 'well, you can get your own food', or 'you make the decision on where we can go. You say what we can eat.' And as much as I appreciated them, looking out for me, wondering what can we do, it also put the entire effort onto me, and that built up over time. And I eventually just told people, 'don't worry about it. I will get my own food. I'll figure something out. You do what you want, all get myself sorted.' And I put myself away. I avoided it entirely. And that, that I wish I didn't have to do. I wish I could just go with them, and spend time with them instead of making the decision of do I risk it? Do I go there and see what I can find, or do I just say no and avoid the situation altogether?

Thank you.



Justin Z., Living with Food Allergies

My name is Justin and I'm from Chicago, Illinois, but I currently live in New York City. I've only known life with food allergies. When I was young, I was allergic to peanuts, tree nuts, sesame, chickpeas, and pineapple. I've outgrown my peanut and pineapple allergies, but remain severely allergic to tree nuts, sesame, and chickpeas. I don't remember my first allergic reaction, but my parents have described it to me many times. I was at a water park near my childhood home when I, as a toddler, had a bite of my mom's hummus wrap. As she describes it, I blew up like a balloon turning red and blotchy. I started wheezing, but thankfully we were very close to an emergency room where I was quickly diagnosed, treated, and released.

I was fortunate to have access to an allergist who was able to quickly see me, diagnose my specific allergies, and counsel my parents through management strategies. When my parents described the experience, they often discuss the fear and anxiety of watching my condition deteriorate as well as the relief of my recovery. Again, I was young. I don't remember this specific experience, but these feelings of fear, anxiety, and relief would become all too familiar during my future food allergy-related emergency department visits and hospitalizations.

As a child, I trusted the adults around me to keep me safe and know how to use my epinephrine auto-injector. When I became old enough, I took on more of this responsibility, bringing my own snacks to events, practicing how to use my auto-injector, and teaching my friends as well. I'm not sure how many of them, other people with food allergies, most of whom have to do this growing process, also once shot it through their thumb accidentally. I'll never forget the first time I had to use my auto-injector for real. I was in middle school, between classes, when I graciously accepted a Chips Ahoy cookie from a friend. I knew cross-contamination happened, but I was young and the label had said it was only processed with my allergens, not that it actually contained any. I just wanted to enjoy the treats my friends brought and I had had snacks with similar labeling before. Nearly all commercial products have some sort of precautionary allergen labeling, and it's near impossible to find anything without it.

Furthermore, these labels feel neither clear, consistent, nor well understood. Shortly into the next class, my arms began to itch and a few minutes later, my chest as well. I next recognized what I feared I might, an itch in my throat, the feeling that it was about to become more difficult to breathe. I was anxious, partially because I didn't have an auto-injector nearby. My school required the nurse to hold on to them. How could this happen? I was embarrassed. Did I try something new? And I was also terrified of what might follow. Before this experience, I had had allergic reactions, but the symptoms were mild or I was too young to remember, or I was close enough to an emergency room or a fire department to get treated.

I went and told my teacher I thought I was having an allergic reaction and she could certainly hear it in my voice as I began to wheeze. She quickly walked me to the nurse's office down the hall and with each step, I heard my wheeze worsen. Almost immediately after arriving at Nurse Ross's office, she administered an epinephrine auto-injector and called 911. They wheeled me out of my school and took me to the hospital and kids talked about it for the rest of the year.

Experiences like this can be traumatizing for young kids as they were in some ways for me.

There's a persistent anxiety that people with food allergy experience. Food is all around us and it's vital to our survival. You can have one great plan for the day and end up spending most of it in the emergency room. And when you've had life-threatening allergic reactions, you fear something as small as a cashew.

I've had reactions since probably around once a year, every other, and some are worse than others. Often they're mild; I know I've had an allergy and as soon as it hits my tongue and can avoid severe symptoms. Other times I don't, and I'll soon begin vomiting, itching, wheezing, and needing my epinephrine. Once I had to be admitted to the hospital because of my respiratory symptoms, which are also often exacerbated because of my asthma. I am most often exposed because I forgot to disclose my allergies to a food service worker. For example, you don't necessarily expect a house dressing to be a Walnut Vinaigrette. Or the other example is when labels are incorrect or cut short due to space constraints in dining halls or store samples, for example, and especially with my non-top eight allergens, this has been particularly difficult, but thankfully with the recent passing of the 2021 FASTER Act, it will become less [difficult.]

I joined the Center for Food Allergy and Asthma Research at Northwestern Lurie Children's Hospital in 2016. Our work has characterized the prevalence of food allergy and exposed the many barriers that food-allergic families face, particularly those with Medicaid, who are significantly underdiagnosed and less frequently seen by a specialist. I've worked as an EMT and am currently interviewing for medical school as a commitment to others that has undoubtedly come from my early and ongoing experiences as a patient. I have been able to thrive, despite my allergies, and am excited for a within-reach future where food allergies can be prevented or treated, and kids and adults can continue to live and enjoy food without fear.



Dr. Kaye C., Parent of a Child with Food Allergy

My name is Kaye and I'm from Charlotte, North Carolina. I'm here today on behalf of my 12-year-old daughter. [She] is a fun-loving, big-hearted seventh grader. She's a competitive dancer, TikTok connoisseur, lover of all things anime, and the Green Bay Packers. She's quite normal actually, with the exception of this thing. [My daughter] was diagnosed with nine food allergens at the age of nine months and asthma around five years old. She currently is allergic to six of the top eight food allergens, in addition to sesame, beef, pork and sunflower seeds.

There are so many wonderful things that I would rather share with you about [her]. However, I'm here to provide a peek into our lives as a family impacted by food allergies. As you can see, [my daughter] did not attend with me today. Why? Because I honestly needed a break from the anxieties that come along with traveling with a child with food allergies.

After a summer of traveling, I didn't have the bandwidth this time. Can we avoid Sundays? Can we avoid flying on the first and last two flights out? Where's the nearest hospital? Can we cook there? Can I talk to the manager? Did you pack the snacks? Is there a refrigerator or a microwave? These are the questions that we must address every single time we leave our home, whether it's five miles down the road or 500 miles across the country.

And truthfully, I needed a break today. This past summer, our family took several trips. They started and ended the same, anxieties about being away from home, stress around deciding where to stay, days of the week we travel, again, no travel on Sundays, and so on. We started our last family trips a few weeks ago in a panic. We were delayed three hours on the plane while sitting at the gate. We only had enough snacks for the short two-hour trip. After an hour and a half of being stuck on the plane, my husband made the bold decision to deboard in search of more food.

The one restaurant determined to be our safe place had closed moments before my husband arrived. He shared with them that our daughter had food allergies and that their restaurant was the only safe place in the entire airport for her to eat. Thankfully, they accommodated us. However, when we arrived at our destination, I realized that due to our flight delays, we were in the red zone. The red zone means that one of our food allergy rules had been broken, avoiding the last two flights. Everything was closed and our usual routine to grocery shopping at our safe place was foiled. The feeling of defeat consumed me and I could see it on my daughter's face. It was consuming her too. It's that all too familiar feeling of deflation. You just never get used to it.

The aforementioned is one of the many challenges we face as a family impacted by food allergies. We are exhausted and it feels as though there is no end in sight. We work to mitigate risk each day, but the anxieties are always there. They never go away. There are times we feel hopeless, especially doing allergy testing. The results of my daughter's most recent food allergy tests revealed no changes. I don't have the heart to tell her the news yet. Another reason why she isn't here today. We were really hoping to cross at least one allergen off the list. Nothing.

And as my daughter gets older, our anxieties increase where our hope fades. Potential dangers that we were able to control were becoming further and further from our reach. And with each new environment comes additional worries. As I mentioned, Carisse started seventh grade a few weeks ago, and FAD came up.

FAD is our family code word for food allergy disclosure. This time it was [my daughter] who brought it up. I gave my husband the look and we knew. [She] wanted it to be in charge of disclosing her food allergies without any input from us. We knew this day in our lives would come. We just didn't know when. Last Friday, [she] attended her first football game alone with friends. All I could think about were the pitfalls: peanuts in the stands, minimum hand-washing, which group of friends did she FAD, whether or not she had a rescue meds with her, what will she eat, while at the same time, trusting that we taught her how to take care of herself. The mental gymnastics are exhausting, but this is our life.

Admittedly, I often imagine what my daughter's life would be like without food allergies. For my family, this would mean improvement of quality of life and day-to-day functioning and overall mental health. It would mean impromptu family trips, stress-free traveling and socializing, independence and autonomy, and eating and sharing the same foods with family and friends. It's ironic that the very thing that's required for basic human survival could actually inflict harm or tragically kill. This is our reality. And even though food allergies have created this life for us, we are hopeful that one day, food doesn't remain a source of stress.



Lisa R., Living with Food Allergies and Parent of a Child with Food Allergies

My name is Lisa. I'm from Cherry Hill, New Jersey. I actually am one of the lucky ones to be able to have food allergies myself, as well as children with food allergies. So, I get to sit on both sides of the playing field. Today, I'm going to share my family's story with you. Most people ask me, will your kids ever grow out of food allergies? Will you grow out of food allergies? But what they don't know is that I grew into all of my food allergies.

I had my first anaphylactic reaction to food that I had eaten my entire life at 30 years old, just a few months after giving birth to my first child. One day I was eating this food without any issues. The next day, bam. It nearly took my life. At the time of the initial reaction, I was in the throes of being a tired, overwhelmed, first time breastfeeding mom. And now as an added bonus, I had become terrified to eat for fear of having another reaction.

During this time, I desperately tried to deal with it in my own way. I found a few foods that I felt safe eating, over and over and over again. I pushed my worries aside because I had to. I quickly became physically and mentally exhausted, yet I had to push it all down, keep it all inside and just keep moving for the sake of my family. Then, just when I thought the anxiety surrounding my own food allergies couldn't get any more stressful, the pediatrician informed me that it was time to start introducing my daughter to solid foods. He gave me a list of suggested first foods to introduce to her, oatmeal, rice cereal, fruit and veggie purees. So solid foods began and things seem to be going well for a while. She had no reaction to foods like dairy or wheat and I was feeling pretty confident that my daughter didn't have any food allergies.

One year later, my confidence was shattered. It was lunchtime and I was home alone giving my daughter her first taste of hummus. She took a few bites of bread with hummus and she seemed to like it. Yes, a parenting win. But then her face and lips quickly started to swell. She began to have mucus pour out of her nose and mouth, and she was crying hysterically, but choking at the same time. I frantically took her out of her high chair and called the pediatrician who told me to call 911. While on the phone with 911, my daughter began violently throwing up on the kitchen floor and then became limp like a ragdoll. I felt helpless, scared, and alone. My daughter was having an emergency and I froze. I had no idea what to do for her and I was an adult who was already living with food allergies.

A few weeks after this incident, we received the first official food allergy diagnosis for my daughter and our lives were forever changed. My daughter was allergic to sesame and garlic. Full disclosure, I didn't even know it was possible to be allergic to garlic. To say my anxiety was high would be an understatement. At this point, in order to keep moving, I had to block out the trauma of my own anaphylaxis and that of witnessing my daughters as well, yet I was paralyzed with fear. I felt as though I was living life on a minefield and at any given time, I could have a misstep that would be the end. I was afraid to eat anything outside of the house for fear that I would have a reaction. I was afraid to let my daughter participate in any event that had food for fear that she would have a reaction. I was afraid to live.

I honestly couldn't tell you how many life events we missed out on because of my fear, but I can tell you that it is not fun to be sitting on the sidelines, watching everyone else do life. In 2016, I hit my breaking point. I had been navigating living with my own multiple food allergies, my daughter's multiple food allergies and had since had another child who also happened to have multiple food allergies, except lucky me, his were completely different from mine and my daughters. I was worn down from managing food allergies for three people with multiple top eight allergens, now top nine allergens, oral allergy syndrome, also known as pollen food syndrome, and food protein induced enterocolitis syndrome, or FPIES, which is non-IgE mediated food allergies.

Up to this point, I had been able to avoid life most of the time, but now my kids are getting older, and they want and deserve to be part of life. I spent hours trying to figure out how to safely attend social events, birthday parties, parties at school and family gatherings. I fiercely advocated at two different schools to persuade the administration to create a 504 Plan to keep each of my children safe and included in all aspects of the school day. I went to the Capitol to advocate for stock epinephrine in schools and better labeling laws.

I want to live without the fear of having a potentially fatal reaction from one wrong bite of food at a restaurant or a friend's house. I want my kids to be included in life and not bullied or made to feel ashamed because of their food allergies. We all deserve to have a full life, because even though our food may be limited, our lives do not have to be. Thank you.



Stephanie L., Parent of a Child with Food Allergies

Hi, my name is Stephanie and I'm from Mountain View, California. I have two daughters with food allergies. [One daughter] is allergic to shellfish and [her sister] is allergic to milk, eggs, peanuts, and tree nuts and has asthma. I'm a human resources professional and I was at work when I received a call from my daycare saying, "Your baby's coloring doesn't look quite right. She looks, well, a bit blue." I was in shock and then panic, as I flew into flight or fight response. I raced to the daycare while calling my pediatrician and got her over to the doctor's office where she received epinephrine and so began our food allergy journey. We had been avoiding milk for [our daughter], as we had done a skin test for allergies before, due to her skin rashes and eczema, but we had no idea what anaphylaxis could look like, or that it was even possible.

We had packed her sippy cup that day, but mistakenly reached for the cow's milk instead of the soy milk carton. Another day at church, there were fruit smoothies to enjoy. Only unbeknownst to us, they were not just fruit. They contained yogurt and fruit. Our three-year-old said her mouth felt funny and then started vomiting a lot, while we were in the car. We drove straight to the ER. When we arrived, I peeled her soiled clothes off to reveal that hives covered the top half of her body. She again received epinephrine there. A third time, we were having dinner at a friend's house and the friend prepared sippy cups of milk for all the children. Not realizing they were milk-filled, I gave one to our three-year-old to drink. After one sip, she stopped. One hive formed, but she started drooling profusely, which could have meant that her throat was closing as she was having difficulty swallowing.

The first three instances of anaphylaxis all occurred while under my care. What I learned was even as her loving mom, I could make mistakes – and a life-threatening mistake is not one you want to make. For activities where other parents often dropped off or did their share of volunteering, I stayed at every soccer practice and gymnastics workout. For every ballet, ice skating, choir and drama performance, where others would volunteer, I needed to volunteer backstage, for I feared that [another] adult volunteer might not know my child and recognize an allergic reaction or how to use an EpiPen if needed. We only vacationed in our state because I was concerned about flying on a plane with our daughter. What if she had an allergic reaction at 50,000 feet with only minutes to respond? Safety was number one; a close number two was emotional safety.

How could I prevent my daughter from feeling left out? Different? Alone? Almost no food in the early years was safe for her at a birthday party where pizza, cake and ice cream were common; all contained milk. With multiple allergens, she would never be able to eat a friend's birthday cake, any party dessert. The most special part of a celebration for a kid was never safe for her. She always brought her own treat and meal. How would she be able to make friends and go on a playdate and someday maybe even go to a sleepover? How would another parent feel when I drop her off and explain what an epinephrine injector is and what signs of anaphylaxis are? A life-threatening reaction? Would they be fearful of inviting my daughter to their home? Would another parent recognize when she's having an allergic reaction and know what to do?

[Our daughter] has spread her wings since the early years, but there are still hiccups. In sixth grade, after several days of skipping her oral immunotherapy dose, she dosed again and had anaphylaxis. She woke in the middle of the night with red, itchy, puffy eyes, and some strange, not red, bumps on her body. We went to the ER and even then, I was in denial that it was anaphylaxis as I couldn't tell whether the non-red bumps were hives. They were hives and we should have given epinephrine at home when we saw the two symptoms. In eighth grade, she was traveling with her class in China and lost her medication on the first day of the trip. She had never lost her meds before.

Luckily, her teacher was carrying her extra set and yet a third set was in her suitcase. My worries as a mom of a food allergic child have changed over time as she became a teen. Gabrielle is a sophomore in high school now and loves going out with her friends. I need to trust that I've taught her what to do if she has an allergic reaction. Will she have remembered to bring her emergency meds with her? Will she recognize if she's having a reaction that requires epinephrine? Will she be able to use epinephrine if she needs it? Will her friends know what to do if she needs help? I'll keep spot checking to see if she has her meds on her and if she's taking her OIT dose.

When she launches from our house, I want her to be safe in the world, wherever she chooses to be in the world.

Session 2 Panel Remarks: Patients' Perspectives on Prevention and Treatments for Food Allergy



Emily B., Parent of Children with Food Allergies

My name is Emily B. I am the mother of two children who bear a significant burden of allergic disease. I live in Kansas City, where I'm a wife, mother, and social entrepreneur. I am the founder and CEO of the Food Equality Initiative and Free From Market. Both of my girls are allergic to peanuts and tree nuts. My youngest, [name], also has eosinophilic esophagitis, better known as EoE.

Our journey began in December 2012, when I introduced peanut butter for the first time. My oldest daughter [name] was only one. After calling our pediatrician, I administered Benadryl and waited for signs for another flare up. Benadryl was effective in stopping the reaction. We went to our local doctor's office that afternoon and [she] was tested for the top eight common allergens. We were prescribed an EpiPen and told to avoid peanuts. A week later, they would call and leave a voicemail, instructing me also to remove milk, eggs, wheat, and soy from [my daughter's] diet. I was overwhelmed.

After requesting a follow-up appointment with our doctor to discuss the food allergies, I was told to find a support group. Over the years, our family has managed multiple food allergies with the addition of asthma, allergic rhinitis, and EoE. One of the greatest challenges has been the burden of food avoidance. The current standard of care for individuals with food allergies is food avoidance. The burden of food avoidance for our family has been steep. The time and effort it takes to shop and read every label every time to avoid accidental exposure is significant. And the additional burden of cost; food avoidance has been financially challenging for our family. I've experienced this firsthand as a mother with limited resources dependent upon nutrition assistance programs.

When [my daughter] was first diagnosed, we did our best to manage the escalating cost of our grocery bill. The average cost of a gallon of milk in Kansas City is about \$4. The non-dairy substitute that was most effective for [her] cost just over \$15 a gallon. This became very difficult for our family to maintain. The markup on gluten-free flour is over 1,000% more than all-purpose flour. I could no longer afford our weekly pancake breakfast; I now only made pancakes for holidays and birthdays.

When my husband, a social worker, encouraged me to enroll in the WIC program when I discovered I was expecting our second child, I was disappointed to find many of the foods we needed were not available through the program. After speaking with local and national WIC officials, I was encouraged to go to my local food bank. My local food bank did not have a USDA clean room and regularly repackaged foods that contain common allergens in the open. I was discouraged from accepting food from the food bank. Finally, I went to a local pantry. I stood in line for hours and watched people leave with carts full of food. By the time it was my turn to shop the pantry, the only safe foods available were two potatoes and a jar of salsa.

This is what led me to start the Food Equality Initiative to address the unmet needs of individuals who must eliminate common foods from their diet for health and wellness, who are also experiencing food insecurity. However, with the growing movement to integrate social care into healthcare, I urge the FDA to consider approving innovative solutions that solve for food avoidance.

While there are many promising pharmaceutical treatments in the pipeline for food allergies, many continue to rely on food avoidance as a measure of protection for patients. Without an approved solution to address food avoidance, we will continue to see wide disparities and food allergy outcomes based on race and income.

I also urge the FDA to take steps to ensure that all new approved drugs meet diversity standards and clinical trials. Like most allergic conditions, food allergy has a significant burden in communities of color, yet new and emerging treatments continue to under-represent communities of color in clinical trials.



Erin M., parent of a teenager with food allergies

I am the parent of a teenager with food allergies.

The food allergy community needs three things right now, accurate and definitive diagnostic tools, accessible therapies with lasting results, and less invasive emergency medicine to combat anaphylaxis.

The diagnostic process leaves much to be desired for patients. After experiencing an infancy covered in eczema and gasping from severe asthma, my son was diagnosed with multiple food allergies based on an IgE test done by our pediatrician. We took our results to an allergist who recommended using an oral food challenge to test against several of the allergens on his list. Within a year, my son had tested out of three allergens: soy, wheat, and corn. Was he overdiagnosed to begin with?

Oral food challenges are cumbersome. First, the test is long in duration and ours required the constant calming of my active toddler. Secondly, my son had already developed some taste and texture versions that made ingestion an exhausting psychological battle. Third, patients and caregivers can view and experience these challenges differently. Now, 16, my son is up for another oral food challenge. To my delight, he might outgrow a single tree nut. He's not sure he wants to do it, though.

Oral food challenges cause a great deal of stress. The idea of consuming a food he has been told to avoid for fear of life-threatening anaphylaxis is unsurprisingly unappealing to him and incredibly anxiety producing. Accurate diagnostics could reduce the need for oral food challenges, overdiagnosis, as well as help direct patients who do have a food allergy towards the correct healthcare pipeline.

Patients need lasting therapeutics that go beyond the peanut and are inclusive of those with other atopic conditions. When my son was just two and a half, we attended a lecture from a prominent clinician in food allergy who spoke to us about desensitization. He said he believed this research was so promising, it might mean a cure for food allergies. I left feeling hopeful, almost relieved that my son wouldn't be saddled with this tremendous burden throughout his childhood, that he wouldn't have to navigate his high school, college and adult worlds fearing that his next bite, next medication, next exposure, might kill him. We discussed this exciting news with our amazing allergist who advised us to wait to join later phases of clinical trials. "Let them work this out first," he said. Our son also didn't qualify due to his asthma, a common comorbid condition that can fatally complicate an allergic reaction. Strike one.

Around age 11, while still waiting for clinical trials to be inclusive of those with asthma, my son began having difficulty swallowing. After several invasive endoscopies, coupled with difficult to manage elimination diets, he was diagnosed with eosinophilic esophagitis, otherwise known as EoE, a second disqualification from most therapies. Strike two. So much for that relief I had felt all those years ago.

Fourteen years later, my son is now in high school, layering his food allergy concerns over the normal turbulence of adolescence, adding food allergy management to the list of things he requires from a good university.

The food allergy community needs treatments that are inclusive of those with comorbid conditions. These are our most vulnerable patients. We also need therapies that target multiple food allergies and look to help patients with allergies beyond the peanut. We need accessible therapies that reduce the burden of this disease with lasting results.

Our community needs affordable, easy-to-use emergency medication.

One night after finishing his regular meal at a trusted safe restaurant, my son, then 12, began wheezing and feeling nauseous. By the time we got home five minutes later, he could barely speak and was pale. I grabbed my epinephrine autoinjector, pulled off the safety cap, evaluated my son one more time and hesitated. Was this anaphylaxis? Would the frightening shot and the association with food allergies cause more psychological damage in its wake? I was looking for skin symptoms, which I learned later do not appear 10% of the time. Was this that time? As my son's pallor turned an unnatural shade of blue, our neighbors, two doctors came immediately over. Looking for confirmation to use the autoinjector, I turned to them, but even they hesitated to use it with concerns over administration and elevated heart rate. Ultimately, we treated his breathing and my son improved, but the takeaway for all of us was clear, early epinephrine would have been key.

(con't)

If a well-informed food allergy parent could hesitate to use epinephrine when it was needed, the risk is that a lot of others would as well. How could we expect our children and teachers, friends, and caregivers to both recognize the symptoms of an allergic reaction and self-administer epinephrine when two doctors debated if it was needed? The injection-based administration of epinephrine is intimidating and requires training to use. We need less-invasive administration of emergency medicine as injectable epinephrine can cause hesitation, which is a barrier to use and a potential danger to patients.

Current therapies are heavily based in the prevention and reversal of symptoms in young patients. As my son nears his 17th birthday, he is also nearing the end of a window for effective treatment. His age is fast becoming strike three. Without treatment, my son's age turns his food allergies into a life sentence. We need options for the 26 million adults who live with food allergies. It's time to make food allergy diagnostics more effective and emergency treatment less invasive. We need approved therapies that are wider reaching and longer lasting. Alongside our industry partners, you can make a difference for the 32 million Americans and hundreds of millions of patients worldwide, who are handicapped by this burdensome and life-threatening condition. Thank you.



Maeve W., Living with Food Allergies

My name is Maeve and I'm from Columbus, Ohio. I'm a 29-year-old, lifelong food allergic patient, allergic to peanuts, nuts, dairy, eggs, shellfish, and seeds. And my comorbid conditions are asthma and eczema. I've passed several food challenges over the last eight years, but as someone who has been deemed too reactive to peanuts, eggs and dairy, OIT has yet to become a viable option for me. I passed challenges to pecans, walnuts, beef, and some fish, which has vastly improved the variety of what I can include in my life. I return to this conversation about therapies each time I have a new panel of allergy tests done, but the number of allergies I have, the degree of those allergies, my age, and my activity level, has not made me a good candidate. This interestingly has never been something that was brought up or offered by allergists and only after becoming more actively involved as an advocate and speaker within the food allergic community, have I come to understand how common this treatment is among my younger peers.

As someone who leads a competitively active lifestyle, I've encountered multiple iterations in my life of what's called exercise-induced anaphylaxis, where training or my heart rate has tricked my body into thinking that something that was a minor reaction should actually be a larger one, and I have become hospitalized. As someone whose career is in strength and conditioning, therefore requiring high energy and constant movement, as well as someone whose personal athletic career is driven in Olympic weightlifting, managing the potential for exercise-induced anaphylaxis is significant. As a result, in a conversation with an allergist, it was recommended to me that I was not a good candidate for therapies, given my history of exercise-induced anaphylaxis, and the degree to which I live with naturally high heart rate.

Additionally, managing the inflammation that would naturally come with any type of allergy treatment would be challenging, given the recovery modalities that are needed for a competitive elite athlete. A previous allergist suggested that after passing a food challenge for eggs and baked goods, that I could continue to eat such baked goods daily to help improve my specific egg allergic response, but I'm unwilling to eat those goods to continue both the healthy lifestyle as well as a competitive lifestyle. And current research has given me no other option.

Additionally, it is important to consider that though the focus of food allergic treatment is oriented towards children, those children do grow up and many do not outgrow or entirely respond to treatment to eliminate food allergies. While schedules for many currently eligible for treatment needs to revolve around school and other youth activities, adults living with food allergies with potentially less malleable immune systems would logistically require different treatment schedules to allow for a robust professional career and active lives.

If there were more FDA- approved treatment options for me, this would lessen systemic reactions if and when they occur. I would have more opportunity and a life filled with the privileges of living without fearful limitations, which others take for granted. I could confidently shake hands in professional settings without feeling anxious that this person may have eaten something that I could react to. I could have eaten at a table in the cafeteria with my peers as a child. I wouldn't need my fanny pack that has my medication with me at all times. I could travel to events like this without needing to research emergency services and supermarkets in the area to make sure that I could eat safely and easily while traveling.

Food allergies have permeated every element of the choices that I've made, the person I've become, and the experiences that I hope to have. Viable treatment to minimize risk of exposure would change every facet of my life and has the potential to change a life-ending accident into an accident of mere discomfort. (con't)

If asked if I would like to entirely eliminate my food allergies from my life, I surprisingly would say no.

Most young adults are changed by one potentially end-of-life experience. I've had both the privilege and frightening opportunity to experience that over 20 times.

And I'm grateful for the perspective that food allergies and these reactions have given me. As an adult with food allergies, I'm constantly asked to leave the room of my own workplace when allergens are present. My food allergies are the butt of jokes from people who feel uncomfortable associating my mortality with something that they take for granted. I've been told that I can't ask the passenger next to me on a flight not to eat nuts. I have been minimized for this experience, but is so accepted in children simply because I still have these experiences as an adult.

I believe that having navigated these reactions has helped me to understand the need for advocates, both for the advocacy of those who experienced overt and accidental discrimination based on their food allergies, as well as more broadly sweeping discrimination of race, gender, and other social markers. This understanding of how it feels to have been discriminated against based on this chronic disability has informed my pursuit of my graduate degree in social work and has shaped my perspective that I gratefully have of the world.

The plethora of near-death experiences have brought into light what is critical for the FDA to understand. That we need more treatment options regardless of age and lifestyle to lessen the propensity for accidental reactions to fatally impact lives.



Priscilla H., Parent of Children with Food Allergies

My name is Priscilla H. and I am a mom to two amazing boys. [Name] is my nine-year-old who is unbelievably intelligent, loves Spiderman, and has severe food allergies. Our journey with food allergies began at [his] birth. We had our hands full. In addition to his inconsolable cries the first year of life, [he] regularly had bloody red cheeks and full-body hives from eczema. The doctors treated with topical steroids. These steroids came with their issues of often making the area worse before it made it better, along with current concerns of long-term effects.

At the time, there was no medical correlation between eczema and food allergies. Reflecting back, I realize that there were signs I failed to fully recognize. It wasn't until he was presented with a banana at roughly nine months by my mother, that his face instantly turned to hives and his skin became clammy. Then I, as a mother, was certain it had to do with food.

Getting an official diagnosis was not easy. I was passed from doctor to allergist to specialist. I was then provided band-aid solutions through ointments and creams and heard statements like, "He'll probably grow out of it."

Eventually a blood test showed that my little man was very allergic to what I felt was almost everything. I would spend the next years in constant battle to get him accommodated in school was less than easy, but I worked to ensure my son's safety by identifying three safe meals with the school cafeteria. Pasta was his go-to and breadsticks.

One afternoon, his nurse called because [name], my six-year-old, thought he had eaten something he was allergic to. The nurse's initial call was with little urgency saying that she thought everything was okay. The next call escalated quickly. The nurse with a tone of alarm asked if I was there yet. I was at home. At that point, all I could hear was my baby screaming and crying in the background, "No, I don't want to. No." My heart sank as I was not there to protect him. My son suffered his first anaphylactic reaction to sesame, requiring an epinephrine and a visit to the emergency room. So many questions and feelings resulted that day, especially regarding the epinephrine treatment. What are the long-term effects? Will there be emotional effects from what my son saw as a larger-than-life needle penetrating his skin? And could there be an easier way?

Fast forward today, my challenges as a caregiver revolve around the future. What is available and what planning is being put into place to seek a cure to this disabling disease? I worry when [he] will be a carefree teenager that has the potential of making a fatal mistake by simply eating. I would like to see additional treatments that go beyond peanut with less burden during therapy. We have tried OIT, which involves lots of testing, labs, and heaps of diligence. The goal was to eat the allergen in increments to gradually build a tolerance that, should you stop, results in loss of progress and could result in having to start all the way from the beginning. There is no ending to it and it is a lifelong management process. You are on a constant tightrope. Should you measure the wrong amount of allergen for treatment, the result could quickly turn to anaphylaxis. Needless to say, this puts tons of stress on the already anxious caregiver.

(con't)

Food avoidance requires us buying non-cross-contact items in the supermarket, which is often hard to find, not to mention costly. Even with avoidance, we are at the mercy of accurate labeling. Avoidance comes with multiple setbacks. Exclusion is often the by-product of this. For my son, it has meant that his limitation to participate in regular activities, such as eating lunch with his friends at school, going to restaurants, and often just feeling like a normal kid. Though we're thrilled that sesame will be added as the ninth major allergen soon, it is vital that all ingredients are labeled in order to make safe decisions. We hope to have comparable treatments to the EpiPen available that are far less scary for the recipient and less intimidating for those having to administer it.

I also hope for early intervention treatments that offer long-term tolerance without lifelong maintenance, as well as expanded treatment options for food allergies and more rapid approval for other top food allergens.

Finally, I hope that the FDA continues to expand their outreach and work with patient advocacy community and trusted messengers. This will help make access more equitable for all with food allergies, especially in urban communities. For my amazing [son], expansion of information and more importantly, treatment, will mean that his contagious smile will continue to fill whatever room he enters without fear of a basic life function, eating, until his golden years. And as a mom, that's all I can ask for.



Dawn G., Living with Food Allergies

Hi, my name is Dawn, and I live in Kansas City, Kansas. I'm 42 years old and a wife, mother, foster parent, spiritual director, and web designer. Eczema, hives, inflammation, and hay fever have always been part of my life. Growing up on a farm in Iowa, it was hard to avoid many allergens. I was embarrassed of my skin and sores. I started allergy shots and antihistamines as a kid. And when my skin got really inflamed, I would go in for a steroid injection or oral prednisone. Sometimes my throat itched when I ate and I took Benadryl.

When I was 20, I was still itching a lot and I tested positive with skin prick and IgE blood test to several foods that I craved and ate regularly. I was diagnosed with severe eczema along with food allergies. I did a strict six-month elimination diet with 10 foods and my eczema improved drastically. Upon reintroducing the allergic foods, now I couldn't eat even a tiny amount of dairy, eggs, pork, or lamb without my throat swelling. Other foods, I was supposed to rotate in my diet so as not to become more allergic to them. This has happened and now I have more allergies than ever, including wheat, corn, oats, nuts, and shellfish.

My allergies continue to change. I can't avoid and rotate everything I should, and the delayed reactions to some foods are sneaky and hard to diagnose. I also have many food sensitivities, which I know are different than allergies, but they are significant to me because they affect my skin, weaken my immune system, and cause inflammation. An ideal treatment would address the food allergies, the environmental allergies, and my weakened immune system that contributes to the sensitivities and inflammation.

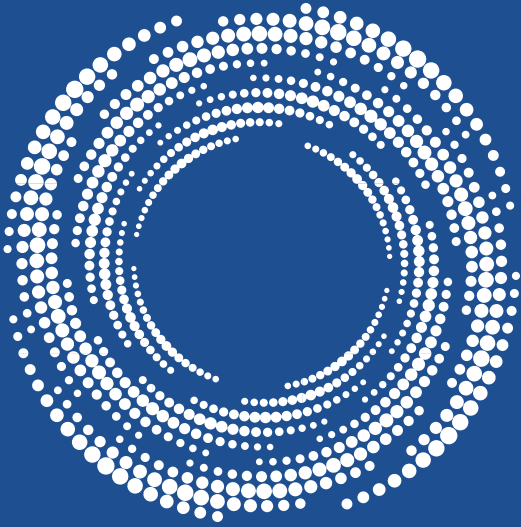
I once did oral immunotherapy with an allergist in Wisconsin. I had three vials to use at home for inhalant antigens, foods, and seasonal allergens. I put antigen drops under my tongue three times per day precisely. I did this for about a year and it seemed to be working, but then I moved to Kansas City and that treatment wasn't available. I liked doing the treatment at home though.

My current preventions and treatments for food and environmental allergies overlap. I take Allegra, Flonase, Qvar, and Singulair, sometimes Zyrtec and allergy eye drops. If I eat wheat, I'm okay for a while, and then I get boils, which has resulted in several very painful trips to the doctor, followed by antibiotics. I recently tried mirtazapine as needed for nighttime itching. It did help the itching, but I couldn't deal with sleeping an extra hour and then still feeling groggy and very emotional. I don't like the idea of being on an antidepressant as an eczema treatment caused by food allergies. I carry Benadryl, albuterol and an EpiPen every time I go out, especially if I might be eating. I usually don't eat out and I avoid places where eggs are being cooked. I still get environmental allergy shots. I do the careful skincare regimen for eczema. My allergist is trying to get me approved for Dupixent for eczema, but I have to try and fail at other treatments first in order to get it covered. This includes steroid creams and now cyclosporine, which is an immunosuppressant drug and seems extreme as a roundabout allergy treatment.

I would like to do treatments with less side effects and ones that are actually targeting the allergic problem rather than bandaging allergic symptoms. Even with all of these treatments, I'm still highly allergic with the total IgE hovering around 2,000 IU per milliliter. All of these allergies wear on me, making my body constantly tired and stiff and they affect my family. All three of my children are around the fifth percentile in weight because they eat like I do.

This year, I started to see a naturopath who helps me with diet and supplements to increase my energy and help my overall wellbeing.

Living with multiple allergies is stressful, but I'm hopeful. I ask the FDA to consider more research in allergy prevention and treatments that address the whole person and the relationship between food allergies and other allergic diseases. Thank you.



Food Allergy Collaborative

