FARE STRATEGIC PLAN

Elevating the Patient Voice Through Research, Innovation and Education
Food allergies are at an inflection point. Daily, we learn of investors, researchers and innovators bringing new ideas in the consumer product goods, pharmaceutical, plant science, bioengineering and research industries to fruition. We are hopeful about the promise of a safer world but alarmed at the rise of the disease.

**Once considered rare, food allergies now affect an estimated 32 million Americans.**

The number of children with food allergies – 5.6 million – has doubled in less than two decades, and the prevalence of peanut or tree nut allergies in children has tripled in only 10 years. Adult food allergies are also on the rise. Among the more than 26 million U.S. adults with food allergies, nearly half developed at least one food allergy in adulthood and more than one-quarter had no food allergies as children.

One in 10 U.S. adults and one in 13 U.S. children report they have experienced convincing food allergy reaction symptoms. Approximately two children in every classroom have a poorly understood disease that makes each encounter with food potentially dangerous – or even deadly. Insurance claims data confirm that medical procedures to treat anaphylaxis, a severe and potentially life-threatening reaction, resulting from food have climbed sharply in recent years, up 377 percent from 2007 to 2016. Each year, 1 million children and more than 2 million adults with food allergies receive emergency treatment for anaphylaxis.

Food allergies are an epidemic for which the cause is unknown and for which the only safeguard is avoidance. As the first therapies await FDA approval, it is critical to accelerate our investments so that we support and create scale for the science that will mitigate risk, identify innovations that can halt the rise of the disease, and ensure that knowledge derived from our investments is disseminated to medical and technically trained professionals working with patients.

We do not know which innovations will ultimately lessen the burden of the disease but FARE is focused on collaborations, innovations and partnerships to move us toward answers more quickly.

FARE is raising $200 million to achieve the critical mass of research and investment needed to create measurable, enduring impacts for food allergy patients and their families. We invite you to be part of this historic campaign to transform the quality of life for the one in 10 Americans with food allergies.

Best regards,
Dave Bunning (Chair) and Lisa Gable (CEO)
Innovation & Transformation: Together, we will help advance change around the world.

FARE is the largest private funder of food allergy research in the world and a critical force within a comprehensive landscape of health and wellness partners.

FARE aims to partner with companies and researchers on an exciting journey of discovery. There is no limit to the potential to make discoveries together. Corporate partners’ product and market capacity affects billions of lives, while FARE activates communities and harnesses an extensive network of researchers and collaborators.

More than half of adults with food allergies have experienced a severe reaction.

More than 40 percent of children with food allergies have experienced a severe reaction.

Claim lines with diagnoses of anaphylactic food reactions increased 377 percent between 2007 and 2016.
EMERGENCE OF PRIORITY INITIATIVES

FARE is transforming research, education, awareness, fundraising, advocacy and collaborations to amplify the patient voice to achieve four aims:

1. **ESTABLISHING** a baseline understanding of the disease to give us insights into how food allergies develop and to discover ways to prevent and cure them

2. **ELEVATING** the quality and accessibility of care by implementing guidelines and training

3. **EXPANDING** the number of therapies in food allergy by reducing barriers to drug development

4. **ACCELERATING** new innovations in treatment, diagnosis and patient care

CONTAINS COURAGE™: A FIVE-YEAR PLAN

Tackling the food allergy epidemic demands game-changing advances in prevention, diagnosis and treatment, as well as outreach to empower the food allergy community. To achieve these key aims, FARE has launched a five-year plan that will drive innovations in food allergy awareness, research and patient care. Contains: Courage™ is a transformative fundraising and awareness campaign highlighting the resilience of people living with food allergies. The campaign concept provides a twist on food labeling. The creative showcases the “ingredients” of real people and powerfully states that they contain courage. These strategic investments and partnerships are critical to meeting FARE’s mission: improving the quality of life and the health of individuals with food allergies and providing them hope through the promise of new treatments.
STATE OF THE DISEASE

There is no approved treatment to prevent food allergy reactions. Patients are advised to avoid their problem foods and carry epinephrine auto-injectors to halt severe reaction symptoms if accidental exposure occurs. A single mistake can be fatal. Coupled with this burden of fear, anxiety, vigilance and isolation are $25 billion in direct and indirect costs shouldered each year by families of children with food allergies.

Important gaps in our understanding of food allergy contribute to the current, inadequate standards of care. We don’t know what causes food allergy or why it has become more common, although new clues are emerging as more researchers join the field. In an era of sophisticated molecular medicine, diagnostic testing for food allergy lags behind. None of the available tests can predict the severity of a patient’s next food allergy reaction. The results of blood tests and skin prick tests are not always conclusive. The most accurate tests – food challenges – exact a barbaric toll of stress and potential danger, especially for children who have been taught to always avoid a food but who are then required to eat that food to see if they react.

SCALE IS REQUIRED

In addition, the progress made to date has not reached all of the families who could benefit from known advancements. While access to specialized food allergy care is improving, it remains limited and some best practices have not been implemented effectively. For example, in 2015, the groundbreaking Learning Early About Peanut (LEAP) allergy study showed that early introduction of peanut foods can prevent many cases of peanut allergy but adoption of the 2017 federal guidelines based on that FARE-funded research has been uneven, particularly among pediatricians and family practitioners.

Recent increases in federal support are insufficient to overcome decades of underfunding: from a 2017 budget of more than $100 for each American, NIH spent less than 25 cents on food allergy research. The initiatives identified in FARE’s plan have been strategically selected to engage and incentivize a coalition of partners – patient advocates; research foundations; clinical networks; government and non-governmental organizations; and consumer, healthcare and biopharma industries – to join us in committing resources to fight the food allergy epidemic.
For more than two decades, FARE and its legacy organizations – Food Allergy Initiative and Food Allergy & Anaphylaxis Network – have worked to amplify the voices of patients with food allergies and to engage the broader community in promoting life, health and hope for all those managing food allergies.

We support the ability of individuals with food allergies to live safe, productive lives with the respect of others through our Education and Advocacy initiatives.

Working across multiple modalities and stakeholder groups, we introduce content and activation opportunities that focus on awareness, inclusion, prevention and emergency protocols.

**PRIORITY INITIATIVES**

- **Provide state-of-the-art, evidence-based education** to patients with food allergies and their families.

- **Support professionals** who require up-to-date education and training in food allergy, such as dietitians, school staff and food service personnel in a variety of settings.

- **Develop meaningful educational materials** that support recent research and innovations that are easily accessible and understandable.

- **Provide educational resources and opportunities** that support the K-12 and college/university settings to benefit students who live with food allergies and their families.
FARE has achieved great successes in advocacy over the years, passing more than 100 pieces of legislation across the country with the help of dedicated advocates who established comprehensive food allergy guidelines in schools, allowed public entities to stock non-designated epinephrine auto-injectors, improved food allergy training in restaurants and much more.

As we look to the future and the challenges facing families with food allergies, we need to ensure that the new and innovative treatments being developed today to desensitize and eventually cure food allergies need to be approved by the FDA and they need to be accessible to the people who need them.

Over the next five years, FARE will be expanding its advocacy capacity and capabilities with a multi-million dollar investment that will allow deeper engagement on the issues most important to our community and will grow the organization’s expertise and skills to better traverse the challenging terrain ahead.

We will utilize best-in-class technology to grow our community of engaged advocates, bringing their personal stories to the decision makers who will help us make needed progress toward all of our policy goals. We will continue to collaborate and partner with other organizations who share our goal of increasing awareness and education around food allergies, and establishing legislation and regulation that address the needs of the community.

**PRIORITY INITIATIVES**

- **Secure enactment of the FASTER Act** (HR 2117);
- **Seek and secure $200 million** in annual federal funding for food allergy research;
- **Reduce regulatory barriers** to development of food allergy therapies;
- **Improve coverage and reimbursement of food allergy treatment**, which will spur new entrants into the market and encourage more allergists to enter the field;
- **Reduce the use of oral food challenges** in clinical trials; and
- **Launch early-intervention trials.**
FARE is transforming research, education, awareness, fundraising, advocacy and collaborations to amplify the patient voice to achieve four aims:

1. **ESTABLISHING**
   a baseline understanding of the disease

2. **ELEVATING**
   the quality and accessibility of care

3. **EXPANDING**
   the number of therapies

4. **ACCELERATING**
   new innovations

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**32 MILLION AMERICANS HAVE FOOD ALLERGIES**

- 45% (11.7M) of food-allergic U.S. adults are allergic to 1+ foods
- >50% of food-allergic U.S. adults have experienced a severe reaction
- 11% (>26M) of U.S. adults have a food allergy
- Nearly 50% (5.6M) of food-allergic U.S. adults developed at least 1 food allergy during adulthood
- <25% of food-allergic U.S. adults have a current prescription for epinephrine
ESTABLISHING A BASELINE UNDERSTANDING OF THE DISEASE

Many fundamental questions about food allergy remain unanswered. Novel research capabilities are needed to drive the discovery of underlying causes and key factors that influence food allergy development and prognosis. FARE’s unique resources include the world’s largest registry of food allergy patients, which provides invaluable real-world data to better understand the burden, needs and healthcare outcomes for this condition. Established in 2017, the FARE Patient Registry is a trove of privacy-protected medical data now available to researchers. Plans are moving forward to add a biobank of medical specimens to the registry’s assets. These tools will help investigators shed light on what causes food allergies, how the body senses allergens, which allergens cause reactions, why individuals become hypersensitive to foods and what causes variation among patients. Planned research projects will validate recent findings on the number of people living with food allergy and accurately measure the burden of disease.

PRIORITY INITIATIVES

- **Prevention and Birth Interventions Studies:** Launch multiple studies involving thousands of infants to study the benefit of using various interventions early in life to help prevent and reduce the onset of food allergy.

- **State-of-the-Art Biomarker Studies:** Support cutting-edge scientific research, facilitated by a Centralized Research Exchange that includes a biobank, a data hub and additional resources to foster collaborations and new grants.

- **Generating Real-World Cross-Sectional Population Analysis:** Leverage the FARE Patient Registry and other real-world data sources to conduct population and health outcomes studies.

- **Validation of U.S. Prevalence Data:** Validate recently published large-scale prevalence and adverse-events studies.

FARE’s unique resources include the world’s largest registry of food allergy patients.
ELEVATING THE QUALITY OF ACCESSIBILITY AND CARE

For patients in 19 states and the District of Columbia, FARE has brought state-of-the-art care and clinical trial enrollment closer to home through the FARE Clinical Network, a nationwide collaborative encompassing 33 centers of excellence. By translating the research conducted at these food allergy centers into best-practice recommendations that are widely communicated and adopted, we can impact the care received by an even broader population of food allergy patients. The implementation of evidence-based guidelines will improve nationwide access to the most effective preventive measures, early interventions, diagnostic tests and therapies available. Educational outreach to allergists, pediatricians and other healthcare professionals will help standardize high-quality care and make it more widely available.

PRIORITY INITIATIVES

- **Evidence Generation and Best Practices:** Employ data analysis and clinical studies to inform standards of care and best practices. Sources of real-world evidence will include data from FARE Clinical Network centers of excellence and collaborations with community clinics.

- **Setting a Path to Future Guidelines:** Work with the community of food allergy stakeholders to create a path for developing and implementing national guidelines for care. We will collaborate to make guidelines widely available and used in practice.

- **Medical Training, Education and Tools:** Co-sponsor education and training programs, including better educating the food allergy community about its options for treatment, such as what is known and unknown about the current practice of in-office immunotherapy using off-the-shelf food products.

33 Centers of Excellence in 19 states and Washington, D.C.

20,000 Oral food challenges given to patients

100,000 Food allergy patients seen at Centers of Excellence
BUILDING ON THE SUCCESS OF THE FARE CLINICAL NETWORK

Since 2015, the FARE Clinical Network (FCN), a nationwide collaborative encompassing 33 centers of excellence, has been successful in providing quality patient care for patients with food allergies.

To further improve upon its mission to ensure that patients with food allergies have access to state-of-the-art diagnosis, care, research and clinical trials, FARE proposes a restructuring of the current FCN model.

A restructured FCN will allow the expansion of sites and the ability to apply funding selectively, depending on the unique strengths of each participating site in order to innovate research and diagnostic methods in the pursuit of discoveries, navigate financial resources in the pursuit of expanded funding and collaborate whenever possible to create efficiencies in the pursuit of a cure.

**DISCOVERY CENTERS OF DISTINCTION:**
World-class research network leading novel, consortia research

**CLINICAL CENTERS OF DISTINCTION:**
Premiere clinical trial network for conducting food allergy trials

**CARE CENTERS OF DISTINCTION:**
Deliver best standard of care
Recent years have seen the development and testing of therapies to treat single-food allergies. Applications to market allergen-based peanut allergy therapies have completed the clinical research phase of drug development and been submitted for consideration by the Food and Drug Administration (FDA). However, such products will not address the full burden of disease for the estimated 14 million American who have allergies to more than one food. The establishment of clinical and regulatory pathways for multi-allergen drug therapies will expand treatment opportunities for patients managing multiple allergies, while all food allergy patients will benefit from regulatory approaches that enable the evaluation of existing immunological therapies as possible food allergy treatments. Targeted support for biomarker research will incentivize the development of improved testing methods that can decrease the frequency of – and eventually eliminate the need for – food challenges in diagnosis and clinical trials.

**PRIORITY INITIATIVES**

- **$1 Million Prize – “Race to Eliminate Food Challenges”:** Create a $1 million incentive challenge to reduce the need for oral food challenges in clinical trials or in practice.

- **Development of Novel Diagnostics and Tests:** Advance strategic areas of biomarker research through directed grants and investments.

- **FDA Path for Multi-Allergen Therapy:** Advocate with the U.S. FDA to establish a regulatory pathway for multi-allergy therapies.
ACCELERATING NEW INNOVATIONS

By dedicating needed resources to food allergy research today, we will create a thriving ecosystem for early-stage investment into new therapies, technologies and start-up companies focused on food allergy. We will foster advances to improve patient care, including preventative and early interventions, non-antigen-based therapies and diagnostics, and digital solutions.

PRIORITY INITIATIVES

■ **Directed Grants for Innovation:** Invest in areas of innovation through a rigorous grants award program, supporting the advancement of promising technologies across the "valley of death," the challenging transition from laboratory success to human clinical trials.

■ **Food Allergy Venture Fund:** Create an independently managed venture capital fund dedicated to food allergy that will focus on early-stage investment and new company creation.
Growing recognition of the food allergy epidemic and advances in biomedical research have brought us to an inflection point, a time with great potential for change. The strategic investments proposed in this plan will lay the groundwork for breakthroughs in food allergy research, education, advocacy and awareness. Every dollar raised will bring us closer to improving the quality of life and the health of individuals with food allergies and providing them hope through the promise of new treatments.