



*Testimony of*

**HUGH A. SAMPSON, M.D.  
CHIEF OF PEDIATRIC ALLERGY & IMMUNOLOGY  
DIRECTOR OF THE JAFFE FOOD ALLERGY INSTITUTE  
MOUNT SINAI SCHOOL OF MEDICINE**

*On behalf of the*

**AMERICAN ACADEMY OF ALLERGY, ASTHMA & IMMUNOLOGY**

*Presented to*

**CHILDREN AND FAMILIES SUBCOMMITTEE  
OF THE HEALTH, EDUCATION, LABOR AND PENSIONS COMMITTEE  
UNITED STATES SENATE**

*Hearing on*

**ADDRESSING THE CHALLENGE OF CHILDREN WITH FOOD ALLERGIES**

**MAY 14, 2008**

My name is Hugh Sampson, and I am pleased to be here today to participate in this important hearing on the challenges confronting food-allergic children and their families. I am the Chief of the Pediatric Allergy and Immunology Division and the Director of the Jaffe Food Allergy Institute at the Mount Sinai School of Medicine in New York. I have spent over 25 years conducting research and caring for children with food allergic disorders. I am also president of the American Academy of Allergy, Asthma, and Immunology (AAAAI), an international organization of over 6,500 allergist/immunologists, allied health professionals, and others with a special interest in the research and treatment of allergic diseases.

I would like to begin by thanking you, Senator Dodd, for holding this important hearing during *Food Allergy Awareness Week*. Families across America will be working this week to educate their communities about food allergies, and it is inspiring for them to know that you are doing the same here in the United States Senate. In addition, I am grateful for your leadership as the sponsor of S. 1232, the *Food Allergy and Anaphylaxis Management Act*, and for your support for Federal policies to protect food allergic-children. Passage of your legislation is critically important to the ability of schools and parents to assure the safety of children with food allergies.

In addition, I am pleased to have the opportunity to express the strong support of the AAAAI for the “*Five Steps Forward for Food Allergy*” initiative announced just yesterday by the Food Allergy and Anaphylaxis Network (FAAN), a national organization dedicated to raising public awareness of food allergies through education and advocacy. I serve as Medical Director of FAAN, and believe that if the five

recommended policy initiatives are implemented, we **will** reduce the incidence of fatal food allergic reactions in our country.

### **Background on Food Allergy**

While I know you are well aware of the impact of food allergies, Senator Dodd, I would like to provide some general information for the benefit of the Committee members. A food allergy occurs when a person's immune system "attacks" harmless proteins in our food. The immune system is the part of the body that usually fights infections and other harmful substances, but in this case the responses are misdirected. A food is misidentified as the body's enemy, and the immune system "fights" the food as it would a parasite or infection.

In children, the most common foods causing significant reactions are milk, egg, peanuts, tree nuts, fish, shellfish, soy and wheat, while in adults the most common foods are shellfish, peanuts, tree nuts and fish. Most children outgrow their allergies to many foods, but not typically to peanuts, nuts, fish, and shellfish, which are often considered life-long allergies.

In the majority of food allergic reactions, the symptoms will begin within minutes after an exposure, although a delay of up to an hour or more is possible. Some reactions can be mild including itchy skin and rashes, itchy mouth, and stomach aches. The more severe and life-threatening anaphylactic reactions can include swelling, hives, welts or itchiness of the skin; digestive symptoms such as severe stomach pain, nausea, vomiting, and diarrhea; respiratory symptoms such as hoarseness, difficulty swallowing, trouble breathing, wheezing, repetitive coughing, and in the worst cases,

throat closing; and reduced blood circulation resulting in paleness, dizziness, passing out, low blood pressure, and even loss of pulse. Sometimes a reaction will subside and then start up again 1 to 3 hours later. There are also a number of gastrointestinal allergies that come on more slowly but can lead to abdominal pain and nausea, weight loss and failure to thrive.

There is no cure for food allergy. Strict avoidance of the allergy-causing food is the only way to avoid a reaction, but even trace amounts of a food allergen invisible to the naked eye, such as residual food on dishes and utensils simply wiped clean, can cause a severe reaction. In some cases the food does not even have to be swallowed. Inhaled food proteins vaporized during cooking have caused severe and even fatal reactions in some individuals. Prompt administration of epinephrine, also called "adrenaline," is the best method we now have for controlling a severe reaction. It is available by prescription as a self-injectable device.

More than 10 million Americans have food allergies, including almost 3 million children. The prevalence is highest in young children, with 6-8 percent of children under four years of age affected by food allergies. The prevalence of food allergies and associated anaphylaxis is increasing. For example, in a national survey, we found that the rates of peanut allergy doubled in children less than 5 years of age from 1997 to 2002, and similar findings were reported in the U.K. Globally, food allergies are most prevalent in industrialized countries like ours with similar lifestyles and eating habits. Through research, we are trying to identify the causes of this dramatic increase. There are several theories under investigation including the question of whether children in our culture are exposed to fewer germs, thereby requiring the immune system to be less

active in fighting germs and somehow making it less effective at identifying certain foods as harmless. The onset of food allergy is often preceded by atopic dermatitis, commonly known as eczema, in which the normal skin barrier is defective. Another theory suggests that contact with creams containing food proteins or residual food on the hands of parents, caregivers and siblings may sensitize these children to the food. Other theories include the rise in consumption of omega-6-containing foods and decreased consumption of omega-3 polyunsaturated fatty acid-containing foods, reduced dietary antioxidants, and excess or deficiency of vitamin D. The majority of young children with food allergies and atopic dermatitis go on to develop respiratory allergies and asthma, something allergists call the “allergic march.” In addition, children with food allergies and asthma are more likely to suffer from severe asthma, and are at greatest risk for severe and occasionally fatal anaphylactic reactions. We believe that a better understanding of the inter-relationship of these diseases is critical to developing new methods to prevent and treat food allergies.

This gives you some idea of the challenges that food allergies present to health care professionals. The impact in the real world of children and families is far more difficult to describe. Food is at the center of almost all of our social functions, and therefore presents a potential threat to the food allergic individual everywhere he or she turns. As I found with my second daughter, who has allergy to walnuts, parents must spend hours in grocery stores scrutinizing labels and phoning companies to get clarification on ingredient labels. In addition, many parents of a child with food allergies live every day knowing their child can walk out the door to day care, or school, or church, or camp, or literally any place in which food is served and end that day in the

emergency room, in the hospital, or in an intensive care unit on a ventilator, or rarely, even dead. Data from an FDA survey published in January of this year, utilizing the National Electronic Injury Surveillance System of selected emergency departments around the U.S., suggest that there are about 125,000 emergency room visits each year for food allergy, and that about 15,000 of these are for anaphylactic reactions, with over 3,000 ending in hospitalizations. Somewhat alarming was the fact that only 43% of the anaphylactic cases were accurately diagnosed by the emergency room staff, a finding frequently reported in similar surveys, emphasizing the need for better health education training and guidelines for health care professionals. Other surveys suggest even higher numbers of anaphylaxis cases, and while accurate data is very difficult to come by, it is estimated that anaphylaxis caused by food allergy results in 100-150 deaths each year in our country. Death can be sudden, sometimes occurring within minutes. You can imagine how the life of an entire family is completely disrupted as they strive to avoid this fate. Far worse, imagine seeing your daughter die in a shopping mall while you are out looking for her prom dress, or your young son go into shock and eventually die from tasting some of a peanut snack unbeknownst to you while your are watching the Super Bowl together, or learning that your son died on a camp canoe trip from an anaphylactic reaction due to residual peanut butter on a knife used to make his sandwich.

### **Recommendations**

As I noted earlier, the American Academy of Allergy, Asthma & Immunology and I, personally, strongly support the “*Five Steps Forward for Food Allergy*” advocacy

initiative announced yesterday by FAAN with the endorsement of nearly 70 organizations from across the country. These five steps include:

1. passage of S. 1232, the Food Allergy and Anaphylaxis Management Act, to help schools create guidelines for managing food-allergic children;
2. creation of a national clearinghouse at the Centers for Disease Control and Prevention on food allergy for the general public as well as health care professionals;
3. development of national guidelines for the diagnosis and management of food allergy for health care professionals;
4. significantly increased funding for research on food allergy and anaphylaxis; and
5. expanded efforts by the U.S. Food and Drug Administration to improve food allergen labeling.

I would like to focus specific attention on the need for expanded research. In recent years, experts have been convened to identify the most promising avenues of research on food allergy and anaphylaxis:

- In March of 2006, the NIH Expert Panel on Food Allergy, convened by the National Institute of Allergy and Infectious Disease (NIAID), released a report detailing an agenda of research questions that should be pursued if we are to succeed in identifying vaccines or improved treatments for food allergy. The report recommended additional basic and pre-clinical research on specific questions; clinical trials to evaluate promising new approaches to the prevention and treatment of food allergies; and

expanded studies of the epidemiology and genetics of food allergy. The report also recommended that efforts be undertaken by the NIH and the FDA to resolve impediments to the design and conduct of clinical trials for the prevention and treatment of food allergy. Unfortunately, due to grossly inadequate funding, most of the research recommended in this report has not been pursued.

- In February of 2006, the Journal of Allergy and Clinical Immunology published the report of a symposium on anaphylaxis convened by the NIAID, the Academy, FAAN and others. This report detailed an agenda of research questions to be pursued to enable us to better understand anaphylaxis and improve methods for prevention and treatment. Again, due to grossly inadequate funding, most of these research initiatives have not been pursued.

Dr. Fauci is to be commended for the initiatives the NIAID has undertaken in the area of food allergy. I have been fortunate to be funded by the NIH for the past 25 years to support my research in food allergy. In that period of time, the field has moved from just trying to understand the manifestations of food allergy to the development of new diagnostic and treatment modalities, several of which are now just starting in clinical trials. However, I can tell you with absolute certainty that unless the Congress provides NIH with significant funding increases for research on food allergy and anaphylaxis, we will NOT make progress toward break-throughs in the prevention and treatment of food allergies. In addition, an investment must be made in the training of



researchers in the field of allergy to pursue a significantly expanded research agenda in the areas of food allergy and anaphylaxis. FAAN is recommending annual increases of \$10 million per year for five years (an additional \$50 million over five years) to bring the budget for research on food allergy and anaphylaxis to a level that will allow us to pursue the research recommended in the two reports I have cited and to support the promising clinical trials underway. I strongly encourage this Committee to formally recognize this need and encourage the Appropriations Committee to provide this additional support at a minimum. I understand that the Federal budget is extremely tight at this time. However, it is important to recognize the size of this problem, over 10 million Americans and their families affected, and that most of the research necessary to improve methods of preventing and treating food allergy simply is not being done.

### **Conclusion**

Once again, I would like to thank you, Senator Dodd, for convening this important hearing. The American Academy of Allergy, Asthma and Immunology looks forward to working with you to achieve the enactment of S. 1232. In addition, we hope you and all members of this Committee will support the initiatives included in FAAN's "Five Steps Forward for Food Allergy" statement and that you will take steps to address the totally inadequate funding for research on food allergy.

Thank you for the opportunity to participate in this hearing. I would be happy to answer any questions.