Peanut Allergy
White Paper

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Executive Summary

The focus of this white paper is to present the current science on peanut allergy, while placing it in the context of food allergy overall. About four percent of adults and four percent of children have food allergies. In children under five years of age, food allergy can approach six to eight percent. Just over one percent of this is due to peanuts and tree nuts, with half having an allergy to peanuts and half to tree nuts. The reported increase in peanut allergy parallels an overall increase in childhood allergic disease.

An allergic reaction to peanuts can vary from mild to severe. Severe reactions can lead to anaphylaxis, which is a potentially life-threatening reaction that can include hives, nausea, and breathing difficulties. For those at risk of an anaphylactic reaction, it is essential to understand all of the facts surrounding self-management. Education about allergy risks and good management practices should be encouraged and widespread.

The allergic components in peanuts are specific identified proteins. There is a misconception regarding the allergenicity of peanut oil. The vast majority of peanut oil used by foodservice and by many consumers is highly refined and processed oil, from which all of these proteins are removed. According to the Food and Drug Administration (FDA) Food Allergen Labeling and Consumer Protection Act of 2004, highly refined oils, which have been refined, bleached, and deodorized are exempted as major food allergens. If an allergic individual is unsure as to whether a product contains or was fried in highly refined peanut oil, that individual should ask the manufacturer or restaurant for clarification.

The Food Allergy & Anaphylaxis Network (FAAN) is a nonprofit organization whose mission is to raise public awareness to provide advocacy and education, to advance research on behalf of all those affected by food allergies and anaphylaxis, and to help individual families cope with their child's food allergies in order to keep children safe.

According to the FAAN, "Studies show that most allergic individuals can safely eat peanut oil (not cold pressed, expelled, or extruded peanut oil - sometimes represented as gourmet oils)." For those who are allergic, they recommend asking the doctor whether or not to avoid peanut oil.

There is promising new research underway to find new therapies for combating peanut allergy. One of these therapies is called oral immunotherapy (See "Latest Research" insert), in which increasing levels of peanut allergen are fed in a controlled research setting.

Although this strategy is still experimental, it has been shown to be effective in a new study published in 2009 in the journal, *Allergy*. It is not clear whether this treatment approach promotes a long term tolerance to the peanut allergen, or if subjects are desensitized to the allergen only if they continue daily treatment.

Until more testing has confirmed a solution, there are many helpful strategies for successful management of peanut allergy that include good hygiene and cleaning practices in foodservice areas, education, planning ahead, and carrying medicine such as epinephrine. However, for a peanut allergic person, the best recommendation is to avoid contact with peanut products.

Concern over peanuts in public places has led to some schools calling for peanut bans. However, bans, which can never be fully enforced, may lead to a false sense of security and put the child at greater risk. There is no evidence supporting the effectiveness of this practice. A more effective solution is to educate students, schools, and foodservice professionals and set up a food allergy management plan.

KEY FACTS

- The data shows that 0.6 - 1.2% of people have a mild to more severe tree nut allergy
- The aroma of peanuts cannot cause allergic reactions
- Peanut oil, when highly refined, does not cause allergies in those allergic to peanuts
- The vast majority of peanut oil used in the United States is highly refined
- It is estimated that the number of deaths from all food allergy in general is about 150 per year
- Proper management of peanut allergy is encouraged and can be highly successful
- Proper management of peanut allergy is not always carried out – one study showed that 50% of children at risk of allergic reactions did not carry epinephrine with them
- While promising new research shows potential strategies to combat peanut allergy, avoiding contact with peanut products continues to be the best practice for prevention of peanut-allergic reactions.

LATEST RESEARCH

A new study in peanut allergic children that was recently published in the journal, *Allergy*, describes a process that has been shown to stop their allergic reactions to peanuts. Small daily doses of peanut flour were given to peanut allergic children over a number of weeks. All of the subjects, including one who had a severe reaction during the testing phase of the study, were successfully desensitized to the peanut allergen. The therapy, called oral immunotherapy, expanded the childrens' tolerance. So much so, that the children could eat up to 10 peanuts – many more than they would ingest accidentally. This data is especially promising, since it was effective for all of the children in the study. However, it was conducted in a research setting and should never be tried at home.

Note: This white paper provides an overview of major highlights related to food and nut allergies. We understand and respect the fact that there is a minute percentage of the population that has peanut allergy. We support the recommendation that peanut-allergic individuals work with physicians to manage and minimize their risk and that the best solution at this time is avoidance of all peanut and nut products for those who are peanut allergic. The body of scientific research in this field is rapidly emerging and we hope that there are additional solutions available to treat peanut allergy in the future. This summary will be updated periodically to reflect the latest research and statistics and any changes in the environment of peanut-allergic individuals.

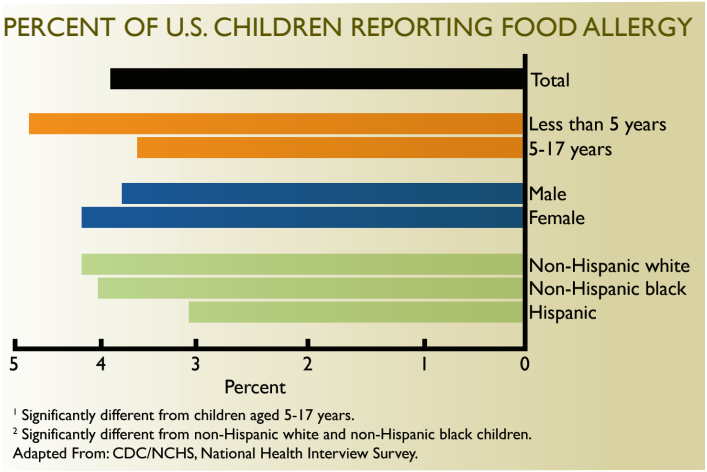
When it comes to school peanut bans, FAAN does not advocate them. They recommend "parents, doctors and school officials work together to develop a plan that best fits their situation."

Introduction

An allergic reaction is caused by a dysfunction in the immune system, whether it is an allergic reaction to food, a bee sting, or to latex. With food allergy, a constituent or ingredient (oftentimes a protein) in the food is considered an invader by the immune system and the body reacts like it is fighting to remove it. About four percent of adults and four percent of children 18 years of age or under have food allergies, with a slightly higher percentage in children under 5 years old.[1,2] Fortunately, some of these allergies can be outgrown over time.

The Centers for Disease Control and Prevention (CDC) reports that children with food allergy are more likely to have asthma or other allergic conditions.[2] Nearly 90 percent of food allergies are caused by these common foods: tree nuts (almonds, walnuts, pecans, cashews, pistachios, etc.), peanuts, milk, eggs, fish, shellfish, wheat, and soy.[3]

Most allergic reactions are not life threatening, but some can lead to a more severe reaction known as "anaphylaxis," where blood pressure drops abruptly and the airways and throat swell, which leads to breathing difficulties. When this is not controlled, unconsciousness and death can occur, so it is important to know how to manage severe allergies, whether they are food or non-food related. Those who are prone to such severe reactions should always carry and know how to use adrenaline (epinephrine) injector pens, which are also referred to as "EpiPens®," as they can provide the time necessary to seek medical attention. Epinephrine is a hormone that is released from the adrenal glands during times of stress. During emergency situations, it prepares the body for action by boosting the supply of oxygen and glucose to the brain and muscles, while suppressing other non-emergency bodily processes, such as digestion.



[1] Significantly different from children aged 5-17 years.
[2] Significantly different from non-Hispanic white and non-Hispanic black children.
Adapted From: CDC/NCHS, National Health Interview Survey.

It is also important to recognize that food intolerances are not food allergies. Food intolerance is a digestive system response rather than an immune system response and can occur when a food is improperly digested. Symptoms take longer to appear, whereas allergic reactions are usually immediate. For example, some people lack the enzyme needed to digest lactose found in dairy products. This inability to digest is called lactose intolerance. Reactions to the wheat protein, gluten, is another example.

Peanut Allergy

A. Prevalence

With increasing news coverage on peanut allergy in the past few years, there may be a misperception that there is a high incidence of peanut allergy in the U.S. and worldwide. However, the numbers show that only 0.6 - 1.0% of people have a mild to more severe peanut allergy,[1,3,4] and studies show that about 20% of peanut allergies can be outgrown.[5] By comparison, about four times as many people are allergic to seafood. As with all allergies, those with a family history of allergy, asthma, or eczema, may be at increased risk.

The National Institute of Allergy and Infectious Disease (NIAID) reports that approximately one in 90 people in the United States, or 1.1%, have either tree nut and/or peanut allergy and the Food Allergy and Anaphylaxis Network (FAAN) has stated that it is about 0.6% each.[1,3]

Why do nut allergies seem to be growing?

The reported prevalence of peanut allergy doubled from 1997-2002.[7] Although there are a number of theories as to why this may be the case, reasons for this increase are not clear. However, the increase parallels an overall increase in childhood allergic disease. Part of the increase may be attributed to the fact that people are more aware of allergy and that more minor allergies are being captured on record. It is recommended that for accurate identification of the condition,

any child suspected of having a food allergy should consult an allergist to be properly diagnosed.

It is interesting that allergies in general, including peanut allergies, are much less common in Asia and Africa where peanuts are staple foods. Peanut-based Ready-to-Use Therapeutic Food (RUTF) has been utilized successfully in newborns and infants for health and growth purposes in places like Malawi, without any presence of allergy, for example. [8] In fact, rates of recovery from malnutrition in these children are about 90 percent. The use of peanuts in RUTF has been called "a revolutionary and inexpensive solution to the childhood malnutrition crisis." [9]

One of the more mainstream theories behind why there is an increase in allergy in more developed countries is called the "Hygiene Hypothesis." [10] This hypothesis basically states that with modern medical practices such as immunizations and a more sanitary environment, our immune systems do not have to fight as they once did, so they become weak. During infancy, our immune systems are supposed to recognize and fight infectious agents and microorganisms, but with less exposure to these, our immune systems could potentially target other exposures from food or the environment.

B. Severity

In those who are severely allergic, reactions to peanuts can occur from ingesting just a trace amount. This can cause anxiety, especially with the parents of peanut allergic children. However, concern has arisen about having a reaction from touching, smelling, or inhaling airborne particles from peanuts.

THE AROMA OF PEANUTS IS SAFE

Smelling the aroma of peanuts is not the same as inhaling peanut particles that could potentially contain the allergenic protein. The aroma of peanuts comes from aromatic molecules called pyrazines. The aroma of peanuts cannot cause an allergic reaction. [13]

In one of the controlled studies that looked at this, 30 children with significant peanut allergy were exposed to peanut butter, which was either pressed on the skin for one minute, or the aroma was inhaled. Reddening or flaring of the skin occurred in about one third of the children, but none of the children in the study experienced a systemic or respiratory reaction. [11] Another study concluded, "Casual exposure to peanut butter is unlikely to elicit significant allergic reactions," unlike ingestion of peanuts. [12]

C. Recommendations for Management

To prevent an allergic reaction, the best recommendation to those with peanut allergy is to avoid intake. There are also important strategies for minimizing the risk of exposure to allergens, which may occur by accident.

Read labels – Sometimes foods can contain added ingredients with peanut allergens. The U.S. Food and Drug Administration (FDA), Health Canada, and the European Union require the major food allergens to be identified on product labels. This can be a helpful approach when in the grocery store. The FDA is also considering a new standard for labels that would provide more information on the likelihood of cross contamination.

Plan ahead – This can be critical to successful management of allergy, such as when dining out or attending a party. Phoning ahead to notify friends, or talking with restaurant staff can help in reducing risk from inadvertent exposure. A "chef card," which lists ingredients to avoid, can also be used. Chef card templates are available through the FAAN website at: www.foodallergy.org/downloads.html.

Practice proper sanitation – Research shows that the allergens from peanuts are easily removed with common cleaning agents. [14] If foods that contain allergens are kept in the home, make sure that all utensils and equipment are thoroughly cleaned with hot, soapy water prior to use to reduce the risk of any allergen contamination. When eating out, allergic individuals or parents can talk to foodservice professionals to verify that all precautions are taken. Staff should be trained to minimize the risk for allergic individuals, such as by preventing cross contamination in food preparation. The 2010 U.S. Dietary Guidelines Advisory Committee plans to include expanded information on this topic in their 2010 report.

Carry medicine – One study showed that almost 50 percent of allergic children did not carry prescribed medication such as auto-injector epinephrine with them to deal with potential exposure to peanut allergens. [15] Since it is critical to use epinephrine within 10 minutes of an anaphylactic reaction, filling a prescription and building the habit of carrying it can prevent any unwanted circumstances. In the U.S., legislation has now been enacted in 35 states, allowing "EpiPens®" to be carried by students with an allergy at school.

Control asthma – Asthma is the main risk factor for death due to anaphylaxis. [16] In those food allergic individuals

who have asthma, it is very important to be regularly monitored by a physician to manage and control symptoms in the best possible way.

Let people know - Wearing a medical alert bracelet or necklace stating that you have a food allergy can be critical for allergic individuals who are subject to severe reactions.

Foodservice professionals should also take special care to minimize the risk of exposure to food allergens for food allergic individuals. Some strategies for reducing exposure to food allergens in the foodservice setting include:

1) Training staff on handing foods that can cause allergy,

2) Sanitizing equipment and workspaces to avoid cross-contamination during food preparation,

3) Posting signs in appropriate areas when foods with allergens are served,

4) Properly labeling any in-house packaged foods that contain allergens, and

5) Having a plan for readily accessing emergency medical care.

In recent years, the presence of peanuts in public places, such as on airplanes, in sports arenas, and in schools has been of concern. The number of airlines and schools that are adopting peanut and/or nut-free measures is increasing. The justification is that the allergens may become airborne and get inhaled, or the natural oils, such as in peanuts, may leave residues behind which contain allergens.

According to research by Dr. Michael Young, airborne exposure consists of small amounts of food protein, which can trigger allergic reactions that usually result in skin reactions or respiratory symptoms.[17] There have been case reports of severe asthma symptoms from airborne exposure to certain foods, but the typical inhalation reaction would be similar to that suffered by a cat-allergic person exposed to a nearby cat: itchy eyes, sneezing, and runny nose. The chance that airborne exposure would cause a life-threatening anaphylactic reaction is very small. Food aromas can cause conditioned physiologic responses, which may mimic some symptoms, but they cannot trigger an anaphylactic response.

Many experts feel that bans, except in situations that involve very young children such as in daycare centers, give a false sense of security. Peanut bans ignore other potentially serious food allergies. School-aged children need to be prepared to understand real-world environments. There is also no evidence that bans are effective. Education of faculty, school foodservice personnel, parents, and students on how to manage food allergies is a more effective approach.

D. Scientific Research

Research has led to isolation of the major proteins (Ara h 1, Ara h 2, Ara h 3), which act as allergens in peanuts. This finding allows for a better understanding of the immunologic responses. Numerous research efforts to advance the understanding of peanut allergy are ongoing and many promising therapeutic interventions are being investigated.

What causes peanut allergy?

Family history, occurrence of eczema-type skin rashes, and exposure to soy protein were associated with the development of peanut allergy in childhood in one study,[18] but there is no clear cut answer as to why one child ends up with a peanut allergy and another does not. Both genetic and environmental factors seem to be involved.

Some researchers have hypothesized that if peanuts are eaten during pregnancy or infancy there is a greater chance that the child will end up with the allergy. A large, long-term study in the United Kingdom is currently underway to evaluate avoidance versus early introduction of peanuts.[19] However, the most current data does not support this theory.

Maternal peanut consumption during pregnancy or lactation had no effect on developing allergy in one study,[20] nor did duration of breastfeeding.[18] Moreover, infants who ate high quantities of peanuts in the first year of life versus infants who avoided them seemed to prevent, not increase the risk of allergy.[21] There was almost a 10-fold higher rate of allergy in schoolchildren who did not eat peanuts during infancy versus those who had eaten an average of 7.1 grams. In addition, infants who were exposed to peanuts in their home environment and ate them were less likely to develop allergy than infants who were exposed, but did not eat peanuts.

In a review of the research published in 2008 in the scientific journal *Pediatrics*, the American Academy of Pediatrics Section on Allergy and Immunology reported on the effects of early nutritional interventions in infants and children on the

A THRESHOLD FOR PEANUTS

Research on finding a "cure" for peanut allergy is ongoing, however, understanding the best ways to manage peanut allergy are also critically important. A new study in the journal *Food and Chemical Toxicology* utilized a statistical modeling approach and reported that there is enough data available to establish a regulatory threshold level for peanut consumption, which would be "sufficiently protective of the population at risk."[38] Although this research is in early stages, it is very promising. Knowing a threshold level of either the highest dose of peanuts consumed that does not cause an effect, or the lowest dose consumed that produces an effect can benefit peanut-allergic consumers, their physicians, the food industry, and public health authorities so that appropriate food safety objectives can be designed to guide risk management.

development of atopic disease (the tendency to develop allergic diseases such as rhinitis, dermatitis, asthma, etc). The review states that there is "no convincing evidence that women who avoid peanuts or other foods during pregnancy or breast feeding lower their child's risk of allergies." [22]

Which strategies show promise in improving the outcome of peanut allergy?

A number of therapeutic strategies to reduce or eliminate peanut allergy are currently being studied. [23, 24] Among these are Chinese herbal medicine, anti-IgE therapy, oral immunotherapy, and vaccine strategies that utilize genes from peanut proteins.

A unique Chinese herbal formula called "Food Allergy Herbal Formula-2" that is being tested by a group at the Jaffe Food Allergy Institute, Mount Sinai School of Medicine in New York, NY is one strategy that shows promise. When this formula was used in mice for seven weeks it prevented anaphylactic reactions for six months following the treatment. [25] The special mix of herbs may help to promote the right environment in the body for establishing tolerance to peanut allergens. The formula is currently being tested at FDA as a new botanical drug in patients with food and peanut allergy.

Another therapy that has shown some success in increasing the threshold of sensitivity to peanut allergens is called anti-IgE therapy. [26] Immunoglobulin E (IgE) is a type of protein (antibody) found in our bodies that functions in the immune system to identify foreign objects, such as bacteria. Peanut-induced anaphylaxis is an IgE-mediated condition. Research studies have shown that anti-IgE proteins administered through an injection bind IgE in our blood and prevent binding to and activation of other immune cells, thereby pacifying the immune reaction. Dosing and efficacy issues with this strategy, however, remain to be resolved.

More recently, a study in the *Journal of Allergy and Clinical Immunology* tested the blocking of different factors involved in mediating anaphylaxis. Specifically, the blocking of the two hormones platelet-activating factor and histamine (at the same time), resulted in significant reductions in the severity of peanut-induced anaphylaxis in mice. [27] In all but one mouse, the reactions were mild.

The most promising emerging strategy is oral immunotherapy using peanut protein, which has been shown to increase tolerance to peanuts. A new study recently released in the journal, *Allergy,* by Clark, et al. gave small daily doses of peanut flour, which contains high levels of peanut protein, to peanut allergic children over a number of weeks and found that they were 'desensitized' to the peanut allergen. [28] The levels of peanut protein were increased two times each week and all of the allergic children, including one that was highly allergic, were ultimately able to eat up to 10 peanuts without a reaction – more than someone would encounter during accidental ingestion.

To add to this, researchers from Duke University Medical Center and Arkansas Children's Hospital recently announced a pilot study at the 2009 American Academy of Allergy, Asthma and Immunology Annual Meeting that also showed success at desensitizing peanut allergic children with oral immunotherapy. Children in this study were fed peanut flour (which contains the peanut allergen) daily with gradual dose increases to challenge their immune systems. After 8 to 10 months, they could eat up to 15 peanuts without a reaction. Even better, after two and a half years of therapy, children who stopped therapy for a month and were then fed peanuts still had no reaction after eating the 15 peanuts. [29, 30]

Although oral immunotherapy remains experimental, it could be extremely valuable to children with severe peanut allergy and to those who have reactions when exposed to very small amounts. The fact that it has been successful for all children receiving therapy, including those who experience anaphylactic shock during initial dose testing is very significant. At this time, researchers in both trials recommend that the children under care in these studies eat a defined small amount of peanut protein each day to stay used to the allergen, however, this is not a public health recommendation. Alternative approaches may hold additional keys to reducing the allergenicity of peanuts. The United States Department of Agriculture, Agricultural Research Service has discovered that using various techniques to treat peanuts, such as pulsed ultraviolet light or the addition of certain compounds like phytic acid or a protein in apples called polyphenol oxidase (PPO) for example, alters the allergenic properties of some peanut proteins. [31, 32, 33]

Peanut Oil

Since peanut oil is pressed from peanuts, some have questioned if peanut oil also contains peanut allergens. This question has confused many who would like to enjoy a Sichuan stir-fry, deep-fried turkey, or other foods cooked in peanut oil.

"Refined peanut oil did not pose a risk to any of the subjects."
British Medical Journal, 2006

The fact is that highly refined peanut oil is different from peanuts, peanut butter, and peanut flour when it comes to allergy. This is because most peanut oil undergoes a refining process, in which it is purified, refined, bleached, and deodorized. When peanut oil is correctly processed and becomes highly refined, the proteins in the oil, which are the components in the oil that can cause allergic reaction, are completely removed, making the peanut oil allergen-free.

The vast majority of peanut oil that is used in foodservice and by consumers in the U.S. is processed correctly and is highly refined.

The FDA Food Allergen Labeling and Consumer Protection Act of 2004 and the Federal Food, Drug, and Cosmetic Act (FFDCA) indicate that highly refined oils are exempted as major food allergens. [34] The Senate Report that summarizes amendments to the FFDCA states "highly refined oils and ingredients derived from highly refined oils are excluded from the definition of 'major food allergen.' 'Highly refined oils' are intended to signify refined, bleached, deodorized (RBD) oils." [35]

Unrefined, "gourmet," "aromatic," or cold pressed oils are the oils that may still contain the proteins that cause allergy. They can also be referred to as "crude" oil. The use of these specialty oils is limited, however, it should be recognized that not all available peanut oil is highly refined. If an allergic individual is unsure as to whether a product contains or was fried in highly refined peanut oil, that individual should ask the manufacturer or restaurant for clarification.

According to the Food Allergy Anaphylaxis Network, "Studies show that most allergic individuals can safely eat peanut oil (not cold pressed, expelled, or extruded peanut oil - sometimes represented as gourmet oils)." They recommend that allergic individuals consult a physician regarding whether or not to avoid peanut oil.

One high quality, controlled human trial published in the *British Medical Journal* in 1997 looked at the use of refined peanut oil by 60 peanut-allergic individuals. The study monitored individuals with severe peanut allergy and showed that they had no reactions to highly refined peanut oil. Researchers concluded that the consumption of refined peanut oil did not pose risk to any of the subjects. [34] Later, in 2000, a study that looked at the allergenicity of refined vegetable oils concluded: "peanut oil presents no risk of provoking allergic reactions in the overwhelming majority of susceptible people." [35] Additional human trials that test highly refined oils in peanut and nut-allergic individuals are critical as this will keep research current and will help to corroborate these findings.

THE FEDERAL FOOD, DRUG, AND COSMETIC ACT STATES:

"(qq) The term 'major food allergen' means any of the following:
(1) Milk, egg, fish (e.g., bass, flounder, or cod), Crustacean shellfish (e.g., crab, lobster, or shrimp), tree nuts (e.g., almonds, pecans, or walnuts), wheat, peanuts, and soybeans.
(2) A food ingredient that contains protein derived from a food specified in paragraph (1),
except the following:
(A) Any highly refined oil derived from a food specified in paragraph (1) and any ingredient derived from such highly refined oil.
(B) A food ingredient that is exempt under paragraph (6) or (7) of section 403(w)."

Resources

The Peanut Institute
P.O. Box 70157
Albany, Georgia 31708-0157
Phone: 888-8PEANUT; 229-888-0216
www.peanut-institute.org

American Peanut Council
1500 King Street Suite 301 A
Alexandria, VA 22314
Phone: 703-838-9500
www.peanutsusa.com

American Academy of Allergy, Asthma & Immunology (AAAAI)
555 East Wells Street, Suite 1100
Milwaukee, WI 53202-3823
Phone: 414-272-6071
www.aaaai.org/

Food Allergy and Anaphylaxis Alliance (FAAA)
www.foodallergyalliance.org/

Food Allergy and Anaphylaxis Network (FAAN)
11781 Lee Jackson Highway, Suite 160
Fairfax, VA 22033
Phone: (800) 929-4040
www.foodallergy.org

Food and Allergy Research and Resource Program (FARRP)
143 Food Industry Complex
University of Nebraska
Lincoln, NE 68583-0919
Phone: 402-472-2833
www.farrp.org/

International Food Information Council (IFIC)
1100 Connecticut Ave, NW, Suite 430
Washington, DC 20036
Phone: 202-296-6540
www.ific.org

National Institute of Allergy and Infectious Diseases (NIAID)
Office of Communications and Government Relations
6610 Rockledge Drive
MSC 6605 Bethesda, MD 20892-6605
Phone: 866-284-4107
www3.niaid.nih.gov/

National Peanut Board
2839 Paces Ferry Road, Suite 210
Atlanta, GA 30339
Phone: 678-424-5750
www.nationalpeanutboard.org

Anaphylaxis Canada
www.anaphylaxis.ca

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