

State of Food Allergies

The Latest Research and Progress

Food Allergy 101

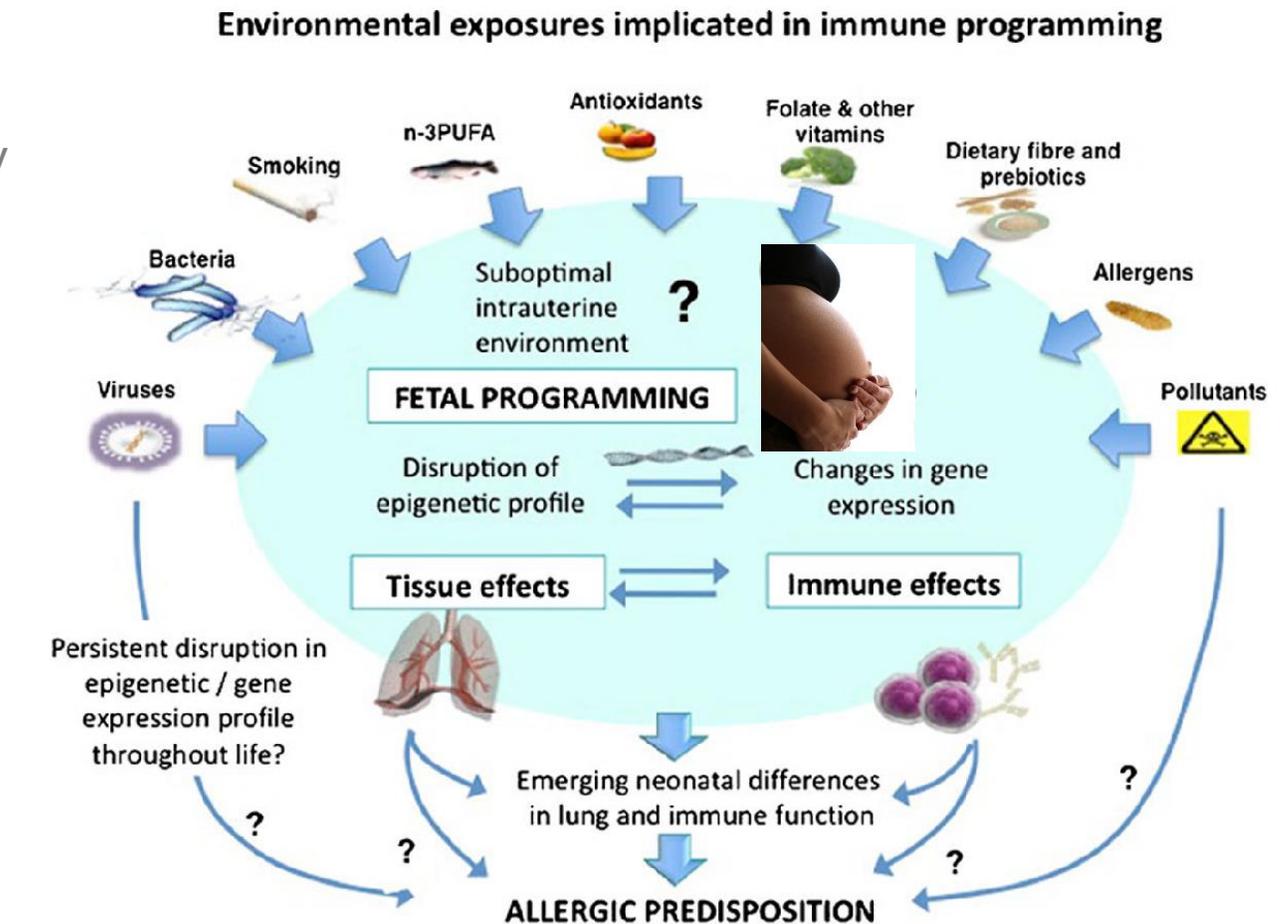
- IgE mediated reaction
- Reaction occurs within minutes or (less commonly) in up to 2 hours
- Reproducible every time the food is eaten
- Sensitization does not always equate to true allergy
- Diagnosis should be made by a board certified allergist
- Reactions range from mild to very severe (potentially life-threatening)
- Affects about 6-8% of children and up to 10.8% of adults
- 90% of food allergy reactions are attributable to 8 foods (milk, egg, peanut, tree nut, fish, crustacean shellfish, wheat and soy)

Food Allergies Are One Piece of an Allergy Puzzle

Eczema * Allergic Rhinitis * Asthma * Food Allergy

Genetics AND Environment Play a Part

Solving the puzzle requires a more wholistic view of the problem



According to the LEAP Study findings...

We can reduce the number of children who develop

peanut allergies **by up to 86% in high-risk infants** by

introducing peanut foods as early as 4-6 months.



The Norm is *Becoming* Feeding Peanut Foods

2015: LEAP Study Published

International Consensus Document Published

2017: NIAID Addendum Guidelines Published

2019: AAP Revised Guidelines Published



But We're Not There **Yet**

Physicians aren't fully implementing the guidelines.

Parents want more information.

We need to *Mind the Gap*.



Learning From the Success of Australia



Changes to infant feeding guidelines for allergy prevention in 2016 were followed by a marked increase in early peanut introduction



Less than 3 IN 10 INFANTS consuming peanut by 12 months in 2007-2011¹...



...to nearly 9 IN 10 INFANTS consuming peanut by 12 months in 2017-2018².



¹ HealthNuts; n = 5,300; ² EarlyNuts; n = 860

Accurate Diagnosis is an Issue

Including self—diagnosis and physician diagnosed

According to the NIAID, 50-90% of self-diagnosed food allergies are wrong. In one meta-analysis, the rate of self-reported food allergy among children was 12%, compared with 3% when confirmatory testing was performed.

Blood and skin tests alone are not diagnostic for food allergies and panel tests are not best practice.

For example, in 111 OFCs performed in 44 children avoiding foods because of positive test results, 93% were tolerant of the avoided food.

Oral food challenges are considered the gold standard.

But they can be expensive and time consuming, and may provoke serious reactions.

Call to Action Within Medical Communities

To use better approach to food allergy testing to:

1. Reduce overtesting.
2. Eliminate panel testing.
3. Offer more oral food challenges.
4. Consider the cost of »mislabeled« an individual with food allergies.
 - Financial
 - Medical/Physical
 - Psychological



Dr. Dave Stukus ✓
@AllergyKidsDoc

Same message being stated repeatedly by experts at #ACAAI19:
#Foodallergy is NOT diagnosed by IgE testing alone...testing shouldn't be done unless the history suggests IgE reactions.

There are zero clinical indications to ever order a large random panel of food allergy tests.

Choosing Wisely
An initiative of the ABIM Foundation

Don't perform unproven (IgG) testing or an indiscriminate random panel of tests, in the evaluation of suspected food allergy.

Appropriate diagnosis and treatment of allergies requires a thorough history and physical examination. The use of other tests or methods to diagnose allergy and treatment is both cost effective and essential for the patient.

For the diagnosis of food allergy is appropriate when the clinical history and allergy is low and a positive skin or in vitro test for the antigen has excellent sensitivity and specificity.

Appropriate avoidance of foods and consistent with an IgE-mediated reaction suggestive for food allergy based on clinical history should be limited to suspected foods.

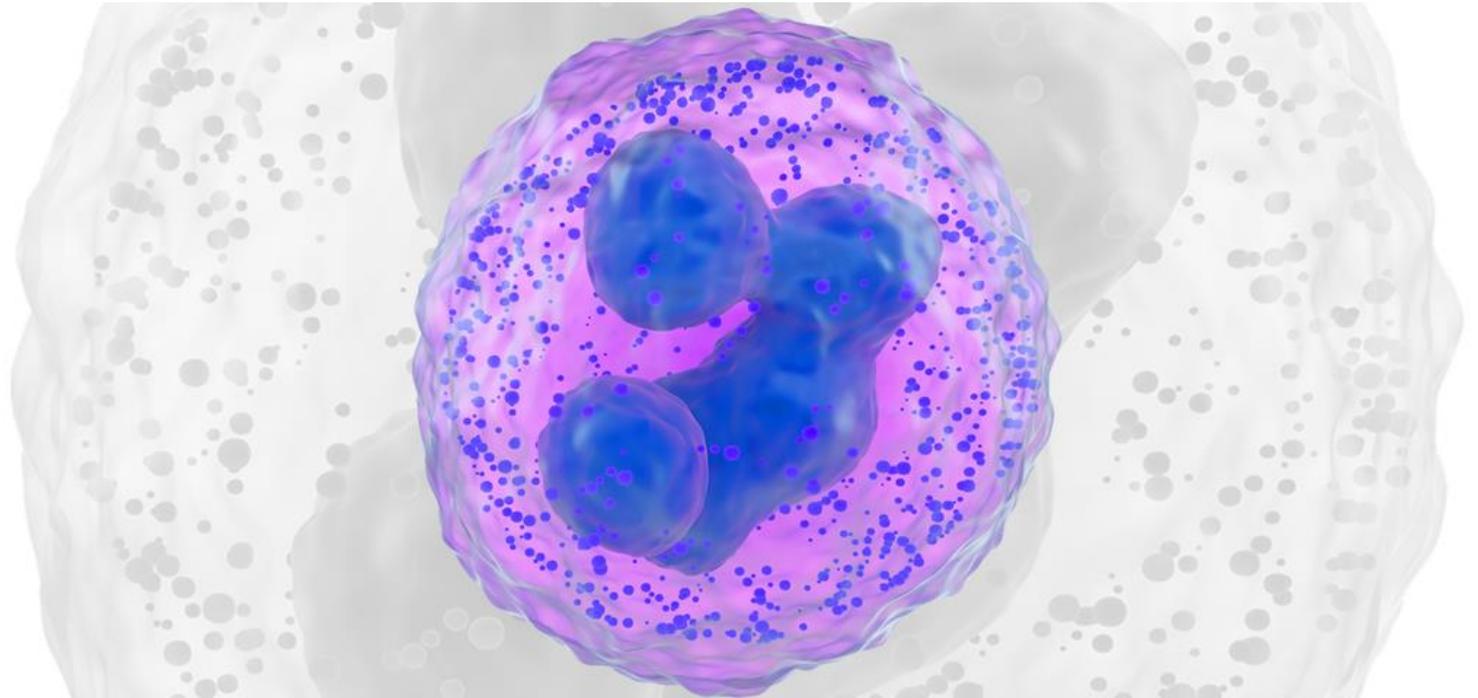
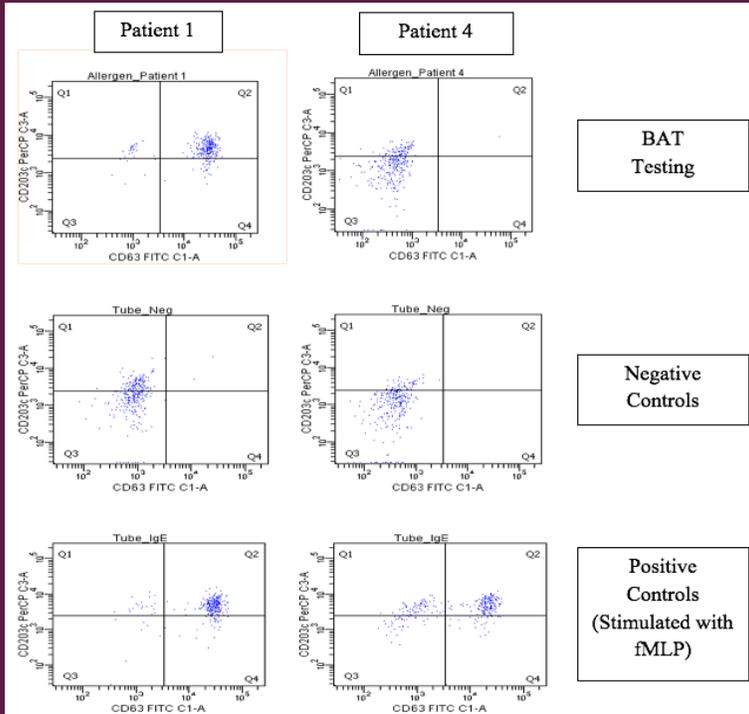
Food allergy is a complex condition with potential for severe reactions.

Better Diagnostic Tools

Mast Cell Activation (MAT)

Basophil Activation Test (BAT)

Epitopes



Immunotherapy: Peanut Allergy Treatments 1.0



Protection through exposure:

Oral Immunotherapy (OIT)

- Has now received FDA approval, **Aimmune's AR101** would desensitize patients to peanut over a period of about six months.
- Afterward, patients would continue to take maintenance doses to maintain desensitization.
- This is a treatment, but not a cure.



The First FDA-approved Treatment for Peanut Allergies:

Palforzia

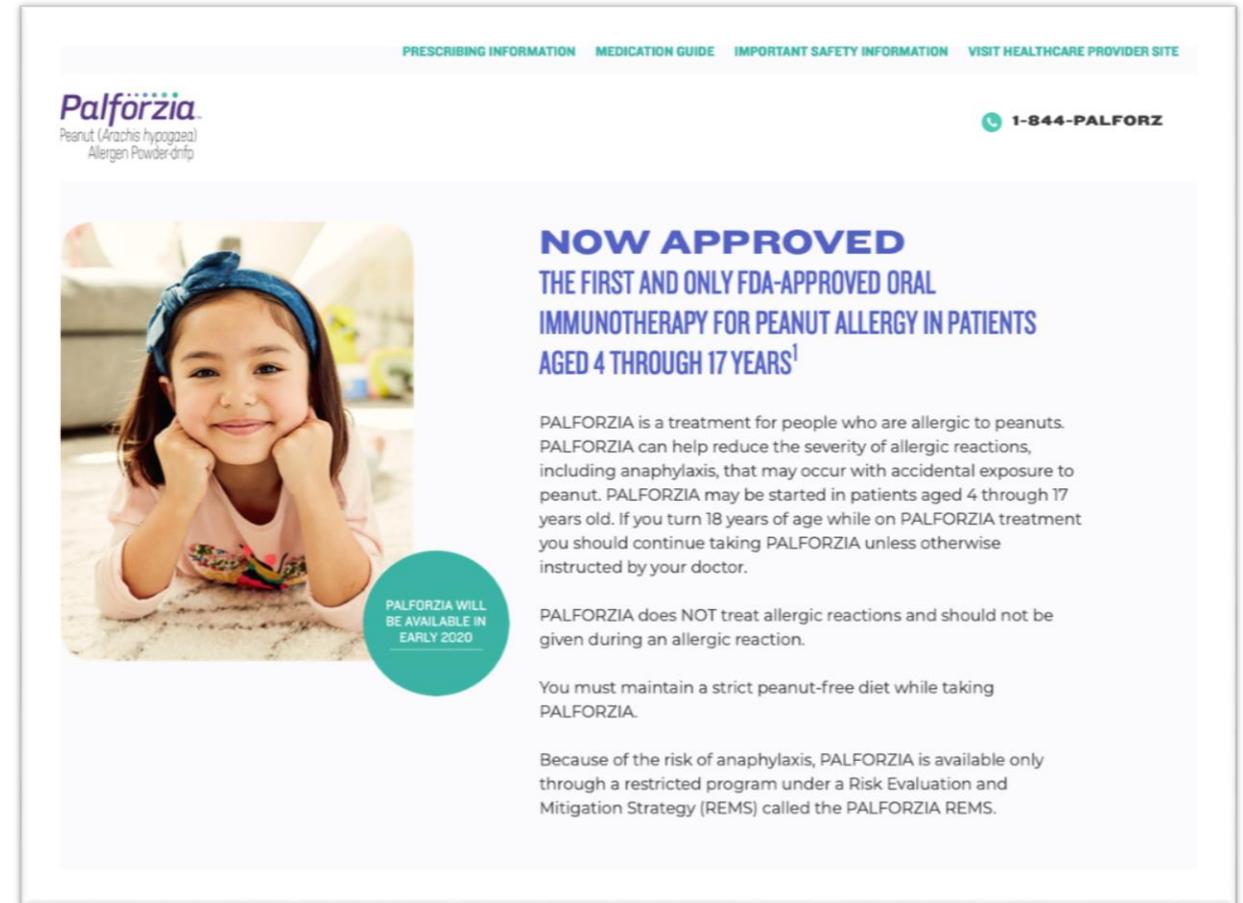
- **Approved January 2020.**

Indications:

- PALFORZIA is an oral immunotherapy indicated for the **mitigation of allergic reactions**, including anaphylaxis, that may occur with accidental exposure to peanut.
- Initiation of PALFORZIA is approved in patients **aged 4 through 17 years** with a confirmed diagnosis of peanut allergy.
- PALFORZIA may be continued in patients 18 years of age and older.
- PALFORZIA is **to be used in conjunction with a peanut-avoidant diet.**

Cost:

- \$890/month
- Unknown duration of treatment/maintenance



The screenshot shows the Palforzia website with a navigation bar at the top containing links for 'PRESCRIBING INFORMATION', 'MEDICATION GUIDE', 'IMPORTANT SAFETY INFORMATION', and 'VISIT HEALTHCARE PROVIDER SITE'. The Palforzia logo is in the top left, with the text 'Peanut (Arachis hypogaea) Allergen Powder-dnfp' below it. A phone icon and '1-844-PALFORZ' are in the top right. The main content area features a photo of a young girl with a blue headband resting her chin on her hands. To the right of the photo is a teal circle with the text 'PALFORZIA WILL BE AVAILABLE IN EARLY 2020'. The main headline reads 'NOW APPROVED THE FIRST AND ONLY FDA-APPROVED ORAL IMMUNOTHERAPY FOR PEANUT ALLERGY IN PATIENTS AGED 4 THROUGH 17 YEARS¹'. Below this is a paragraph of text: 'PALFORZIA is a treatment for people who are allergic to peanuts. PALFORZIA can help reduce the severity of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. PALFORZIA may be started in patients aged 4 through 17 years old. If you turn 18 years of age while on PALFORZIA treatment you should continue taking PALFORZIA unless otherwise instructed by your doctor.' Another paragraph states: 'PALFORZIA does NOT treat allergic reactions and should not be given during an allergic reaction.' A third paragraph says: 'You must maintain a strict peanut-free diet while taking PALFORZIA.' The final paragraph reads: 'Because of the risk of anaphylaxis, PALFORZIA is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the PALFORZIA REMS.'

Protection through exposure:

Epicutaneous Immunotherapy (EPIT)

- **DBV'S Viaskin** delivers biologically active compounds to the immune system through intact skin.
- Aims to desensitize by delivering compounds in small quantities into the outer layers of the skin.
- Resubmitted to FDA 2019.
- Could be available mid/late 2020.



What to Know **About Immunotherapy**

OIT & EPIT do not **CURE** food allergies.

There are risks and benefits.

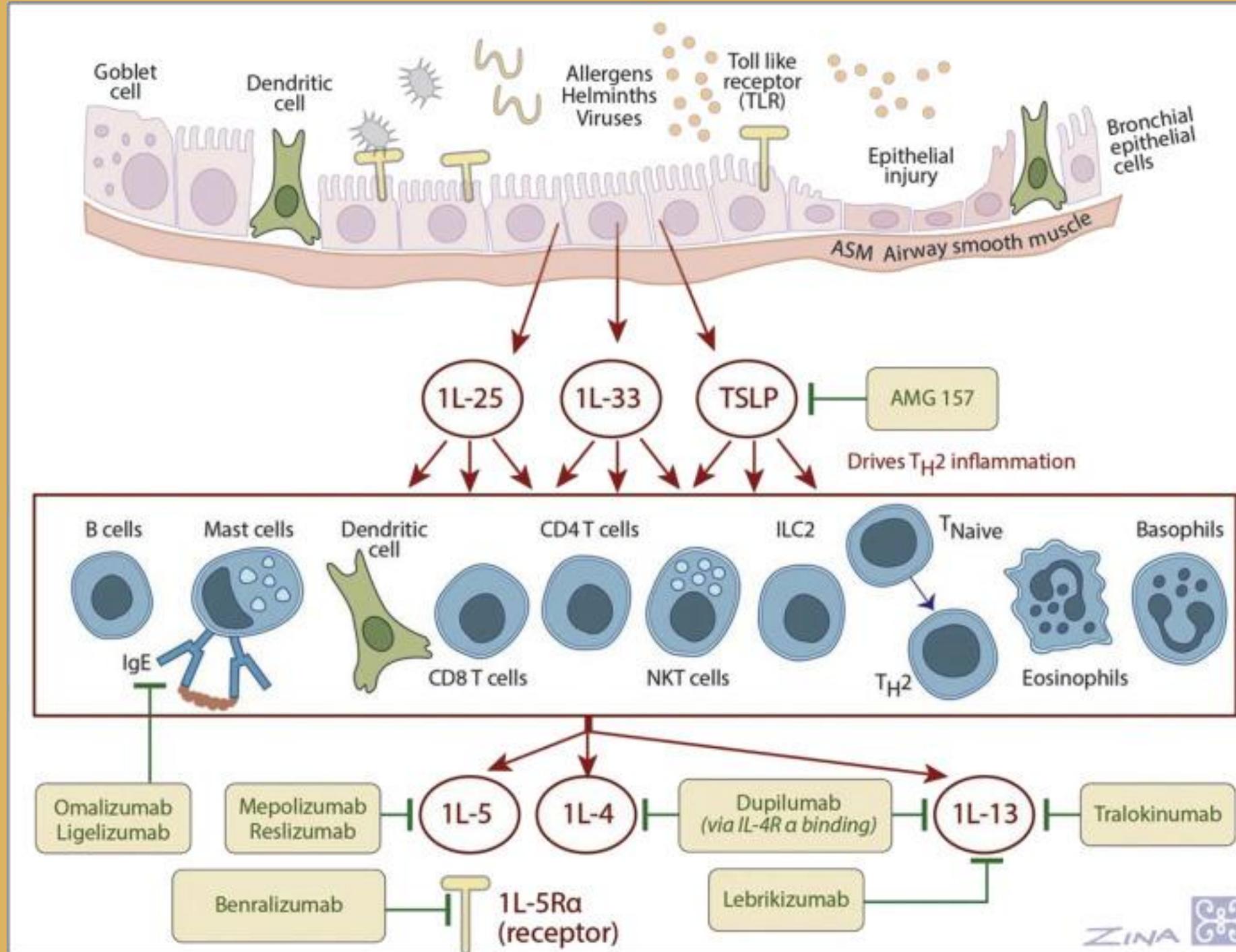
Controversies exist.

Some people will still choose avoidance.

Other co-treatments may make immunotherapy safer and more successful.



Peanut Allergy Treatments 2.0

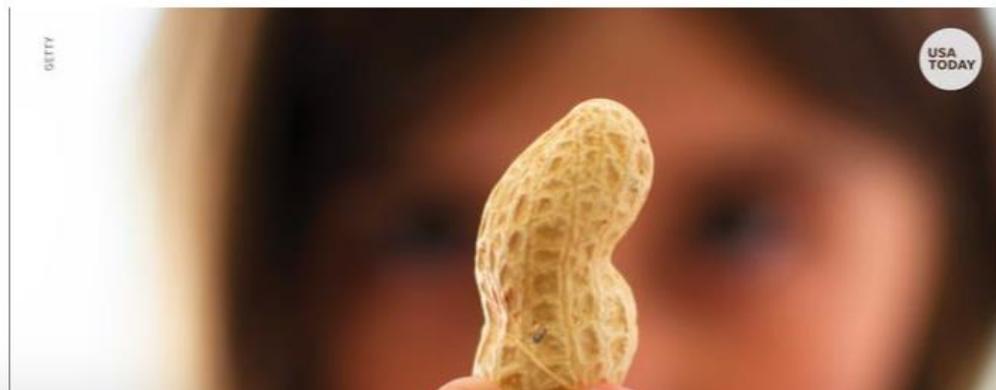


HEALTH

Peanut allergy shots? A new Stanford-led study shows an antibody injection could prevent allergic reactions

Kristin Lam USA TODAY

Published 9:00 a.m. ET Nov. 14, 2019 | Updated 11:20 a.m. ET Nov. 14, 2019



Dr. Dave Stukus @AllergyKidsDoc · Nov 15

Use of biologics holds promise for treating [#foodallergy](#) not by curing the condition, but by blocking a signal/response if a food is accidentally ingested.

It's like a fairly specific layer of protection & security blanket.

It's not a desensitization such as oral immunotherapy

3 1 4



Dr. Dave Stukus @AllergyKidsDoc · Nov 15

Biologics are not ready just yet to use for [#foodallergy](#):

- Need more data regarding dose, duration, safety, expected outcomes, optimal patient candidates

- These are EXPENSIVE, typically >\$1000 per injection

- Injections are likely long term, some every 2-4 weeks

2 1 4



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A fascinating approach in the future may be to use biologics 1st to offer protection from reactions, then start oral immunotherapy (or another form) to offer a better path towards desensitization.

This may lessen side effects/reactions. Still need to sort out MANY details & cost

1 1 12



Huge amount of money now targeting food allergy treatments – and peanut allergy is in the bullseye.

More ‘Novel therapies’ under study

- Vaccines, injectable and nasal, using modified proteins
- Probiotics
- Enzyme blockers
- Microbials for fecal transplant
- PREVENTION: Diet Diversity?

Food Allergies Are a Dynamic Area of Study

- Revisions to the guidelines?
- Ongoing efforts for early introduction of all allergens
- New, better diagnostic methods
- More coverage of immunotherapy & emerging treatments
- Better understanding of influence of diet diversity, microbiome and epigenetics

