

---

# Oral Immunotherapy and Viaskin<sup>®</sup> Peanut for Peanut Allergy: Effectiveness and Value

Public Meeting – June 11, 2019



INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW

WIFI: TCEGuest

---

# Welcome and Introduction

- **Why are we here today?**
- **Unmet need for patients:** My son struggles daily at school. He does not feel safe when I am not around because he is worried that no one else will know what to do if he has a reaction.
  - Parent of child with peanut allergy, AAFA Survey Response
- **Impact on caregivers:** I feel I operate under higher levels of anxiety all the time. Particularly when [my son] is out of my care. He has never had a severe reaction but one day I got a call from his school that they suspected he was reacting to an unknown exposure and I had to rush over to his school to assess him myself. I have frequent flashbacks to this and imagine it happening again...
  - Parent of child with peanut allergy, AAFA Survey Response

---

# Welcome and Introduction

- **Why are we here today?**
  - New mechanisms of action often raise questions about appropriate use, cost
  - Increasing health care costs affecting individuals, state and federal budgets
  - Benefits of independent evaluation and public discussion of the evidence on effectiveness and value

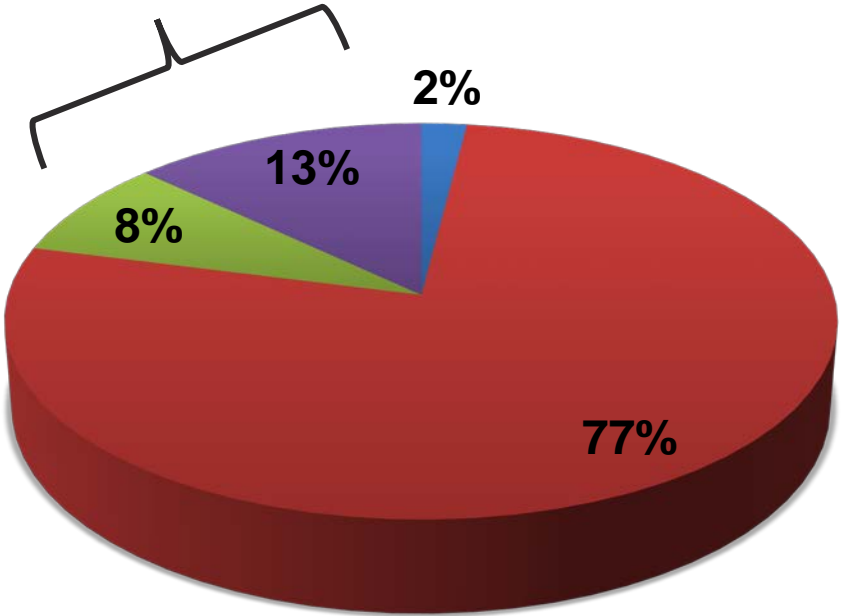
---

# Welcome and Introduction

- California Technology Assessment Forum (CTAF)
- The Institute for Clinical and Economic Review (ICER)

# Sources of Funding, 2019

ICER Policy Summit Only



## Funding Sources

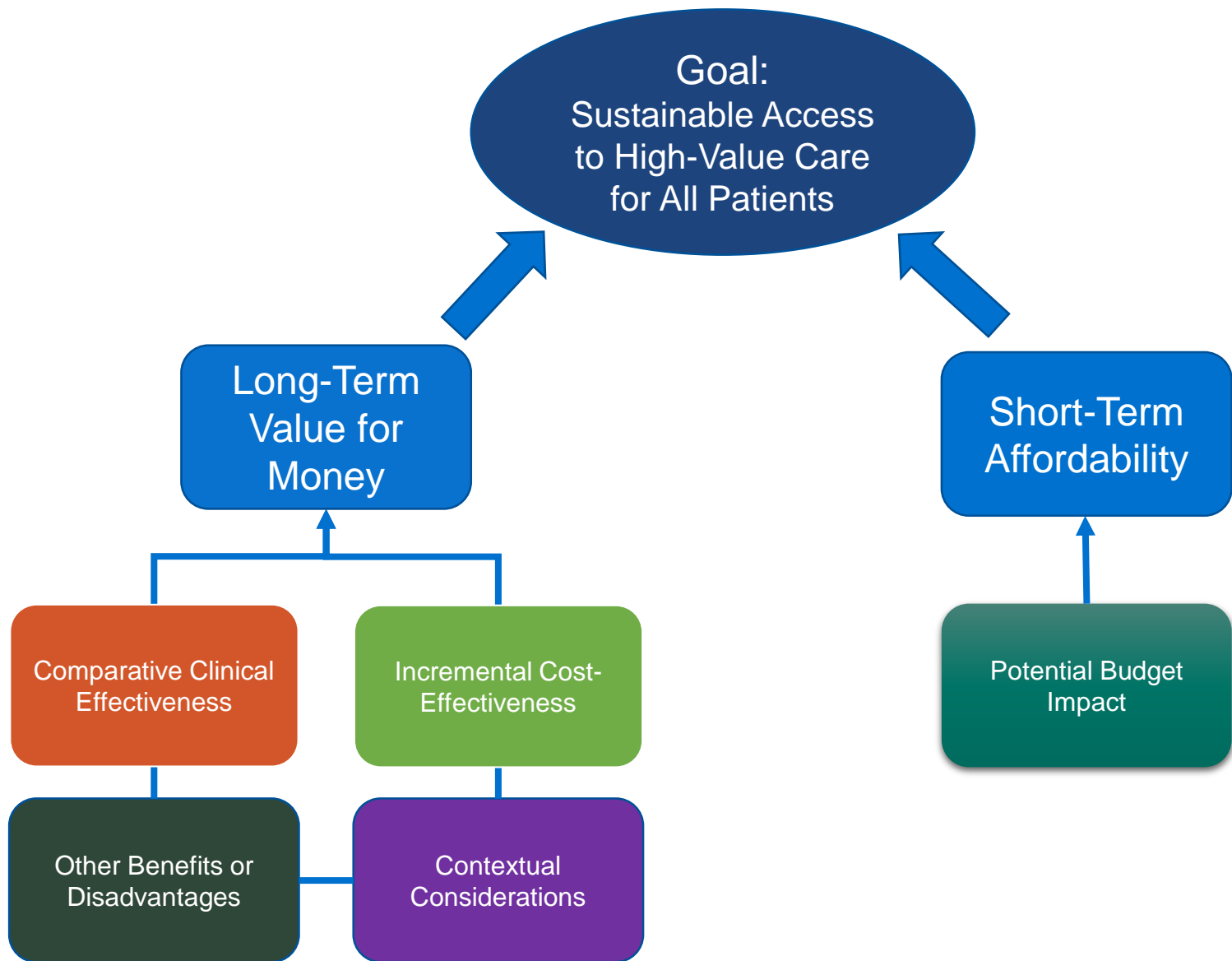
- Government Grants and Contracts
- Nonprofit Foundations
- Health Plans and Provider Groups
- Manufacturers

---

# Welcome and Introduction

## How was the ICER report on treatments for peanut allergy developed?

- Scoping with guidance from patient groups, clinical experts, manufacturers, and other stakeholders
- Internal ICER staff evidence analysis
- University of Washington cost-effectiveness modeling
- Public comment and revision
- Expert report reviewers
  - Ruchi S. Gupta, MD, MPH
  - Nurry Hong
- How is the evidence report structured to support CTAF voting and policy discussion?



---

# Agenda

- 10:00am:** Welcome and Opening Remarks
- 10:15 am:** Presentation of the Evidence  
**Evidence Review:** Jeffrey A Tice, MD, UCSF  
**Caregiver Survey Presentation:** Kenneth Mendez, MBA, Asthma and Allergy Foundation of America  
**Cost Effectiveness:** Greg Guzauskas, MSPH, PhD, UW
- 11:25 am:** Manufacturer Public Comments and Discussion
- 11:45 am:** Public Comments and Discussion
- 12:00 pm:** Lunch
- 1:00 pm:** CTAF Vote on Clinical Effectiveness
- 2:00 pm:** Break
- 2:15 pm:** Policy Roundtable
- 3:30 pm:** Reflections from CTAF
- 4:00 pm:** Meeting Adjourned



---

# Clinical Experts

- **Ruchi S. Gupta, MD, MPH**

- Professor of Pediatrics and Medicine, Northwestern University Feinberg School of Medicine
- Director, Center for Food Allergy & Asthma Research (CFAAR);
- Director, Science & Outcomes of Allergy & Asthma Research Program (SOAAR)
- Disclosures
  - Dr. Gupta has received grants from Aimmune Therapeutics and has served as a medical consultant for DBV Technologies and Aimmune Therapeutics

- **Matthew Greenhawt, MD**

- Associate Professor of Pediatrics, University of Colorado School of Medicine
- Children's Hospital Colorado
- Director, Food Challenge and Research Unit
- Disclosures
  - Dr. Greenhawt has served as a paid consultant for Aimmune Therapeutics and has received honorarium while serving as a member of physician/medical advisory boards for Aimmune Therapeutics and DBV Technologies

---

# Patient Experts

- **Nurry Hong**

- Chief of Strategy and Innovation, Food Allergy Research & Education (FARE)
- Disclosures
  - FARE receives financial support from multiple sources, including DBV Technologies and Aimmune Therapeutics.

- **Caroline Moassessi**

- Patient Advocate
- No conflicts of interest to disclose

---

# Evidence Review

**Jeffrey A. Tice, MD**

Professor of Medicine

University of California San Francisco



INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW

---

## Key Review Team Members

Serina Herron-Smith (ICER)

Judith Walsh, MD, MPH (UCSF)

## Disclosures

We have no conflicts of interest relevant to this report.

---

# Background: Peanut Allergy

- Most common childhood food allergy
  - Up to 2% of children
- Reactions are common, but death is rare
  - Accidental exposures 5%-20% per year
  - Anaphylaxis/Epinephrine use 1%-2% per year
  - ~4 deaths per year over 10 years in US
- Impacts on child's social activity and parental anxiety are important considerations
  - AAFA Survey
- Approximately 15-20% outgrow by adulthood

---

# Current Treatment

- Strict peanut avoidance and immediate use of epinephrine for reactions
- No FDA approved treatment
- Goals of new therapies
  - Reduce reactions to accidental exposure
  - Improve quality of life
  - Reduce anxiety
  - Still require peanut avoidance and epinephrine

---

## Interventions Considered

- **AR101:** Standardized peanut flour orally
  - Dose increased every two weeks
  - Minimum 12 visits to physician
  - Maintenance dose 300 mg daily
- **Viaskin Peanut:** Patch to back
  - Number of hours increased weekly over 3 weeks
  - No additional visits for dose escalation
  - 250 mcg protein to skin 24 hours a day
- **Oral immunotherapy:** No standard approach

---

# Systematic Review Results

- **AR101, Aimmune**
  - PALISADE Trial, *NEJM* 2018
  - Bird *et al.*, *JACI* 2017
- **Viaskin Peanut, DBV Technologies**
  - PEPITES Trial, *JAMA* 2019
  - Sampson *et al.*, *JAMA* 2017
  - Jones *et al.*, *JACI* 2017
- **Oral Immunotherapy (OIT)**
  - 2 Trials – not included in economic modeling



---

# No Network Meta-Analysis / Indirect Comparisons

- Heterogeneity of trial populations
  - Ages 4-11 versus 4-17 years
  - Maximally tolerated dose 100 mg versus 300 mg
- Heterogeneity of trial outcomes
  - Double blind oral food challenge
    - Different dose escalation protocols
    - Different definitions for eliciting or tolerated dose
    - Objective versus subjective criteria for stopping

---

# Oral Immunotherapy (OIT)

- 2 poor quality RCTs, 2 case series
- Start low, increase to target maintenance dose
- Maintenance dose: 125 mg to 5000 mg daily
- Successful desensitization: 21% to 49%
  - No standard definition
- New systematic review and meta-analysis
  - Chu et al, 4/29/2019, Lancet.

---

## Chu et al, Lancet 2019

- 12 RCTs, n=1041, median age 8.7 years
- Risk of anaphylaxis: OR 3.1 (1.8-5.6)
  - No difference build-up versus maintenance phase
- Epinephrine use: OR 2.2 (1.3-3.8)
- Serious AEs: OR 1.9 (1.0-3.7)
- 4/12 trials reported quality of life measures
  - No significant differences

---

## Summary OIT, Chu et al, Lancet, 2019

- “In patients with peanut allergy, high-certainty evidence shows that available peanut oral immunotherapy regimens considerably increase allergic and anaphylactic reactions over avoidance or placebo, despite effectively inducing desensitisation.”

---

# Study Design and Populations

|                    | AR101            | Viaskin Peanut   |
|--------------------|------------------|------------------|
| Phase 3 Study      | PALISADE         | PEPITES          |
| Ages               | 4-17 years       | 4-11 years       |
| Baseline Age       | 34% 12-17 years  | Median 7 years   |
| Peanut Sensitivity | ED $\leq$ 100 mg | ED $\leq$ 300 mg |

ED: eliciting dose

# Primary Benefits

|                               | AR101                          | Viaskin Peanut  |
|-------------------------------|--------------------------------|---|
| Phase 3 Study                 | PALISADE                       | PEPITES   |
| Definition of Desensitization | Tolerate 600 mg peanut protein | ED 300 mg<br>if baseline $\leq 10$ mg<br><br>ED 1000 mg<br>if baseline $\geq 30$ mg |
| Primary Outcome               | 67.2% versus 4.0%              | 35.3% versus 13.6%*   |
| Quality of Life               | Not reported                   | Not reported  |

\*PEPITES did not meet its prespecified outcome: lower bound of 95% CI for the difference from placebo  $>15\%$ : 21.7% (12.4% - 29.8%).

---

# Primary Harms

|                        | AR101                | Viaskin Peanut        |
|------------------------|----------------------|-----------------------|
| Phase 3 Study          | PALISADE             | PEPITES               |
| Severe or Serious AEs  | 5.6% vs. 1.6%        | 4.7% vs. 0.8%*        |
| Discontinuation        | 21% vs. 7.3% (13.7%) | 10.5% vs. 9.3% (1.2%) |
| Discontinuation for AE | 11.6%                | 1.7%*                 |
| Use of Epinephrine     | 14% vs. 6.5%         | 9.2% vs. 3.4%         |

\*AEs in PEPITES reported only if investigator thought it related to the patch.

---

# Controversies and Uncertainties

- Primary benefit: quality of life, but no results reported in the trials
- Surrogate outcome: desensitization
  - No accepted/standard definition
  - Varies even within manufacturer
- Uncertainty about long term outcomes
  - Activities, anxiety, quality of life, use of Epi
  - Sustained unresponsiveness? Tolerance?



---

# Summary 1

- **AR101**

- High rate of desensitization, but many dropouts and an increase in AEs, especially GI, and epinephrine use. No data on quality of life.
- P/I: promising but inconclusive compared with strict avoidance and rapid use of epinephrine due to uncertainties in benefits and harms and increased short term harms in pivotal trial

- **Viaskin Peanut**

- Low rate of desensitization, fewer dropouts but an increase in AEs, especially dermatologic, and epinephrine use. No data on quality of life.
- P/I: promising but inconclusive compared with strict avoidance and rapid use of epinephrine due to uncertainties in benefits and harms and increased short term harms in pivotal trial

---

# New Results from European Academy of Allergy and Clinical Immunology, Portugal, June 2019

- ARTEMIS: AR101 RCT 9-month results, n=175, ages 4-17 years
  - Tolerate 1000 mg: 58.3% vs. 2.3%, p<0.00001
  - Tolerate 600 mg: 68.2% vs. 9.3%
  - Tolerate 300 mg: 73.5% vs. 16.3%
  - Systematic allergic rxn: 12.1% vs. 2.3%
  - Epinephrine use: 6.8% vs. 2.3%
- ARC004: 6-month extension of PALISADE
  - 117/314 (37%) on continued therapy: same rate of AEs
  - 110/314 (35%) on continued therapy: QOL improved from baseline as measured by the FAQLQ

---

# Summary: AR101 and Viaskin Peanut

- **AR101**

- High rate of desensitization, but many dropouts and an increase in AEs, especially GI, and epinephrine use. No data on quality of life.
- **P/I: promising but inconclusive** compared with strict avoidance and rapid use of epinephrine due to uncertainties in benefits and harms and increased short-term harms in pivotal trial.

- **Viaskin Peanut**

- Low rate of desensitization, fewer dropouts, but an increase in AEs, especially dermatologic, and epinephrine use. No data on quality of life.
- **P/I: promising but inconclusive** compared with strict avoidance and rapid use of epinephrine due to uncertainties in benefits and harms and increased short-term harms in pivotal trial.

---

# Summary: OIT and Comparisons

- **Oral Immunotherapy**

- I: Insufficient evidence due to poor quality trials and lack of standard dosing

- **Comparisons Among Therapies**

- I: Insufficient evidence due to the lack of head to head trials and the differences in patient populations and outcome definitions that preclude indirect comparisons

---

## Public Comments Received

- AR101 should have high certainty rating (either A or B)
- ICERs rate of accidental exposure based on 20 year old, 83 patient Canadian Survey
- ICER understates the risk of dying in adolescents
- AR101 and Viaskin Peanut were granted Fast Track and Breakthrough Designation by the FDA as far back as 2012 for Viaskin Peanut

**Questions?**

---

# Caregiver Survey

**Kenneth Mendez, MBA**

President and CEO

Asthma and Allergy Foundation of America



INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW



**KIDS WITH  
FOOD ALLERGIES**  
A Division of the Asthma and Allergy  
Foundation of America

# My Life With Food Allergy Survey

*An overview of select data from parents of children with peanut allergy*



Asthma and Allergy  
Foundation of America



## KEY FINDINGS: CAREGIVER BURDEN

- FA has a major impact on many caregivers' mental, social and emotional well-being.
- Mental/emotional health impact was particularly high among some parents; fear, anxiety and worry were common themes throughout the survey.
- FA families experience a loss of normalcy leading to adjustments in decision-making and daily routines.

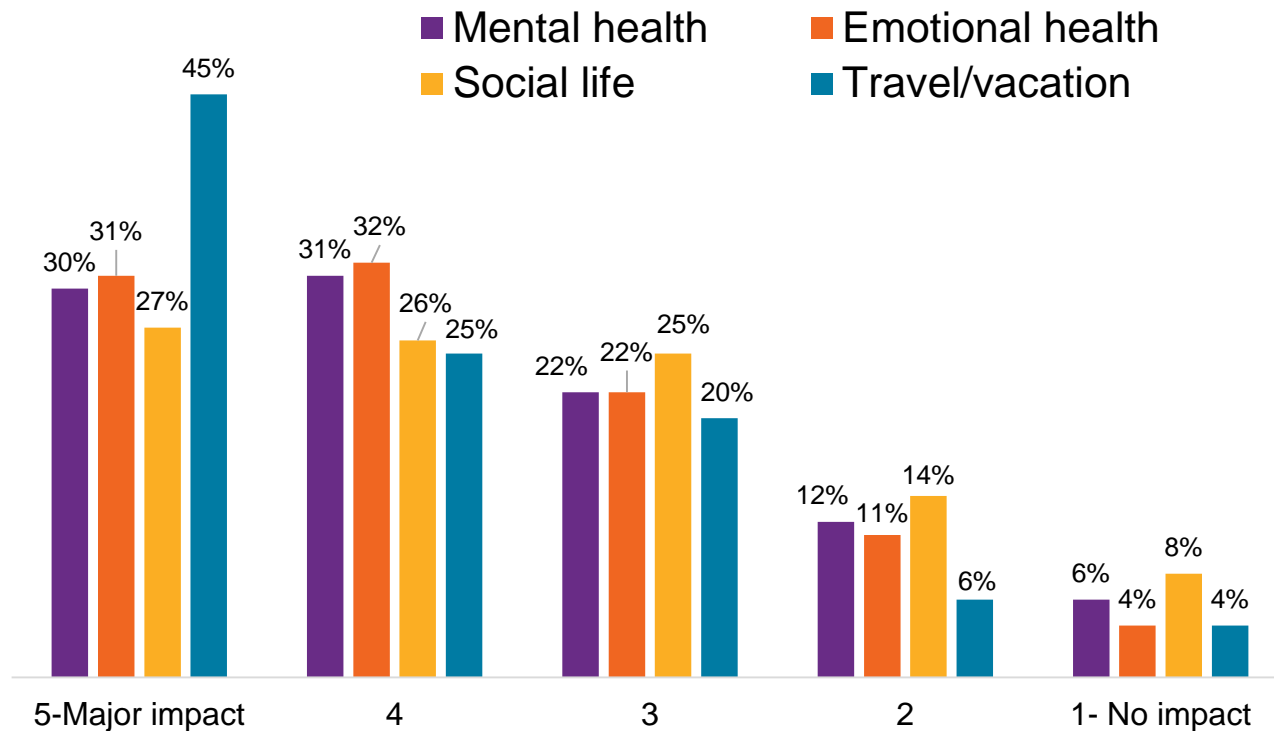
# KEY FINDINGS: FINANCIAL IMPACT

- For some families, daily realities and needs for caring for children with FA presented a major financial burden.
- Some families have had to make career decisions based on FA, leading to negative financial impact on the entire household.
- FA can also present a major time burden for some families.

# KEY FINDINGS: PATIENT'S (CHILD'S) QUALITY OF LIFE

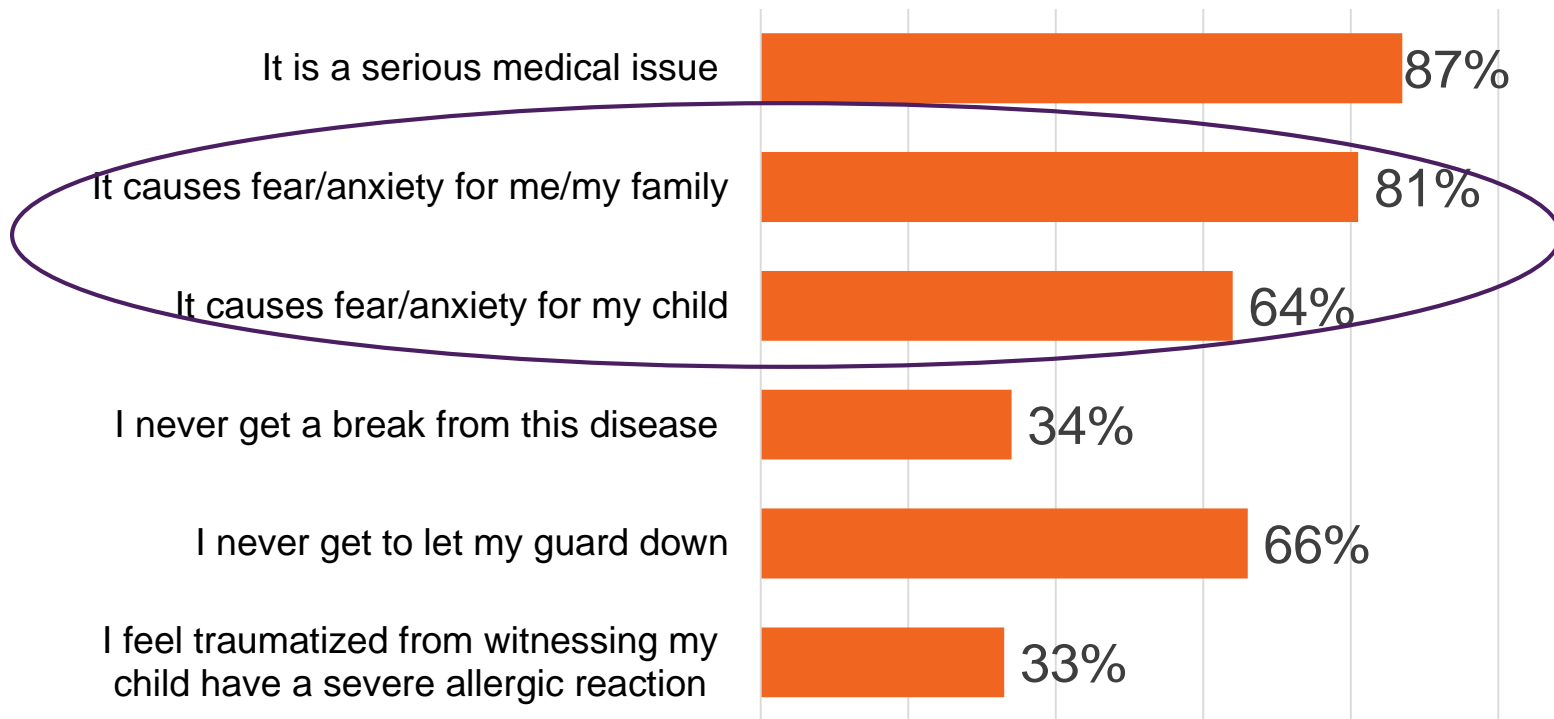
- Peanut desensitization and tolerance could positively impact their child's quality of life

# Food allergy has a major impact on many caregivers' mental, emotional and social well-being.



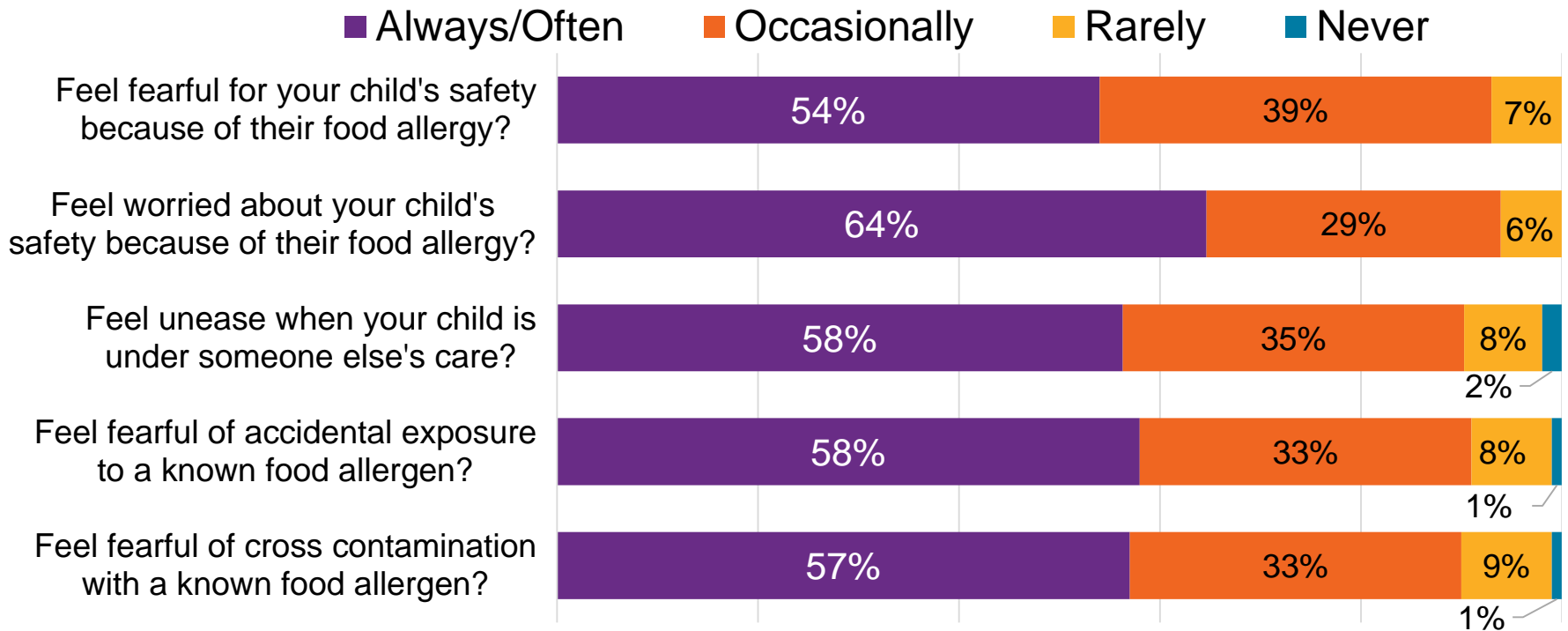
PARENT SURVEY, peanut allergy, N=853

# Caregiver anxiety scores higher than the perceived anxiety of the pediatric patient.



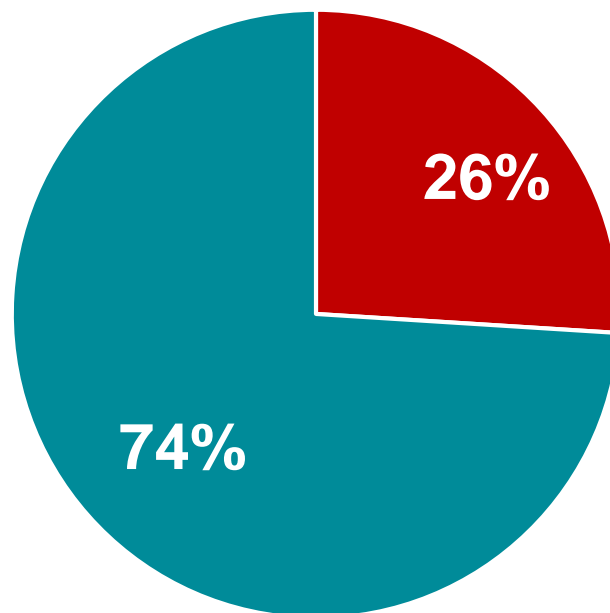
PARENT SURVEY, peanut allergy, N=853

# Prevalence of fear, worry, and unease



PARENT SURVEY, peanut allergy, N=853

# Do you see (or have you seen in the last five years) a mental health professional (such as psychologist, counselor or therapist) related to your child's food allergy?

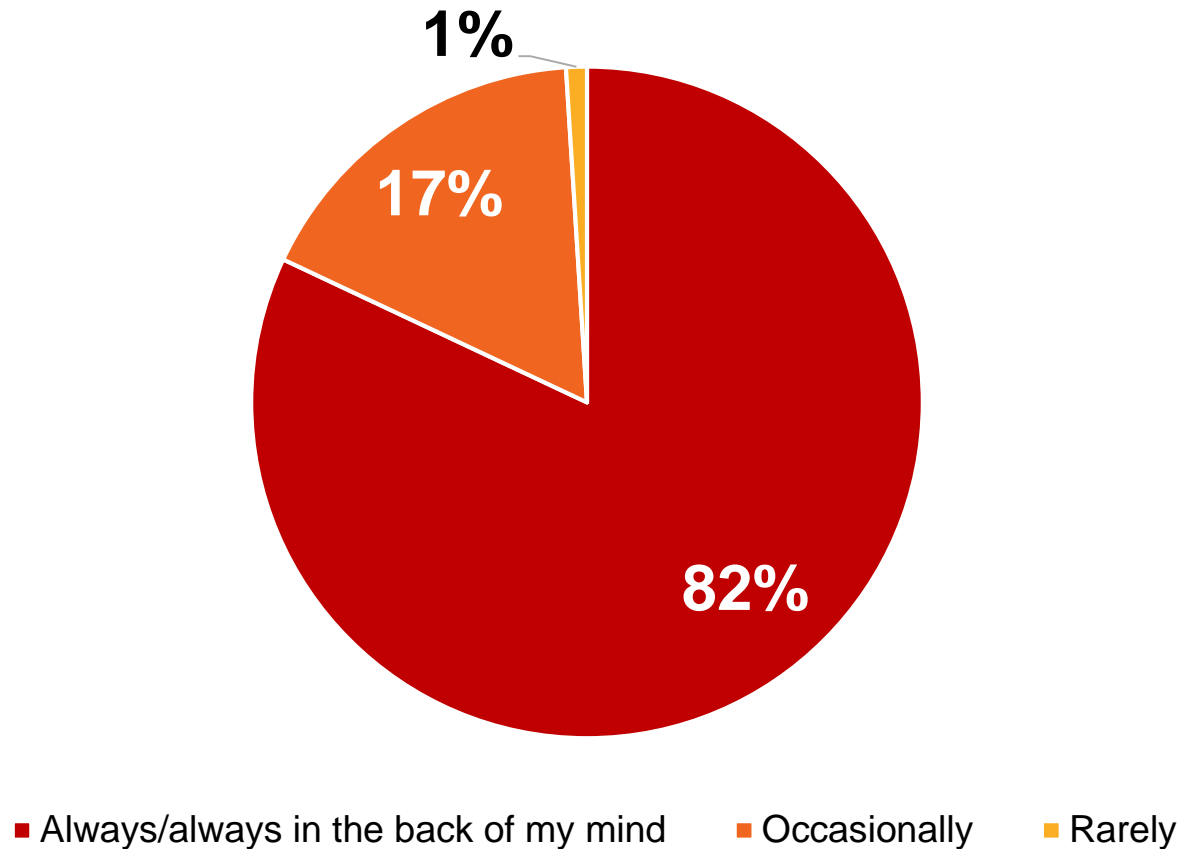


■ Yes

■ No

PARENT SURVEY, peanut allergy, N=853

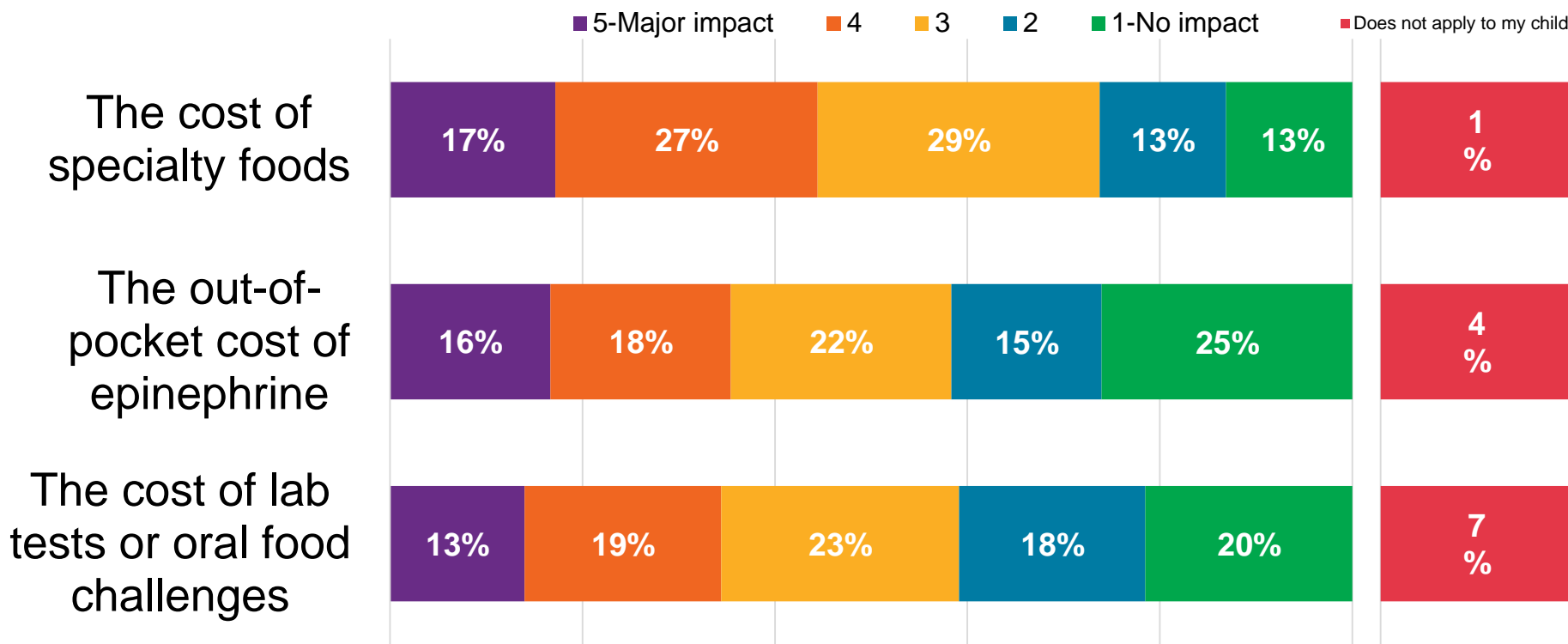
# How often do you think about your child's food allergy/allergies?



PARENT SURVEY, peanut allergy, N=853

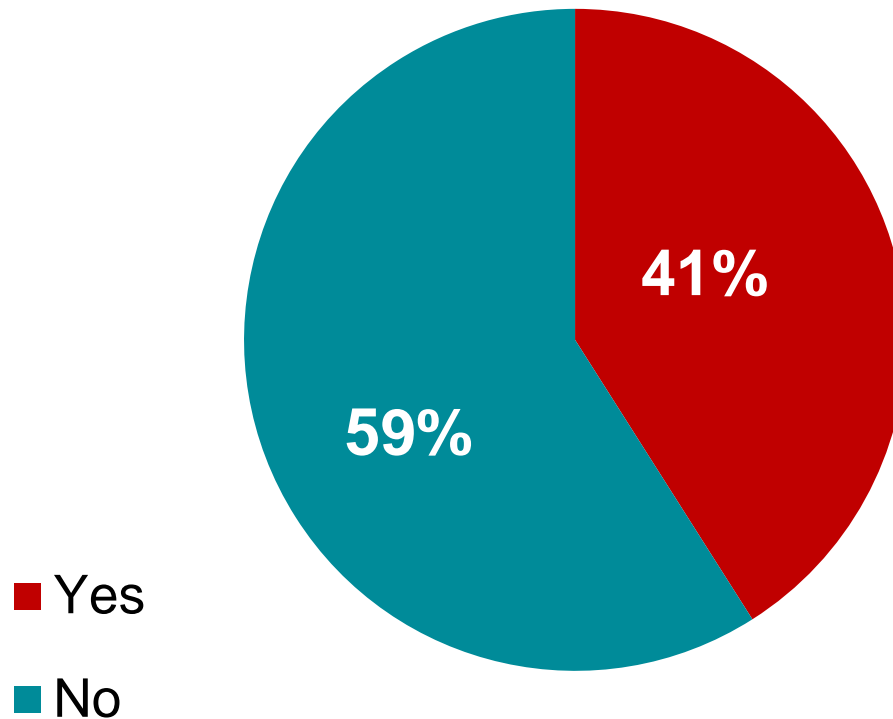


# For some families, daily realities and needs for caring for FA children presented a major financial burden.



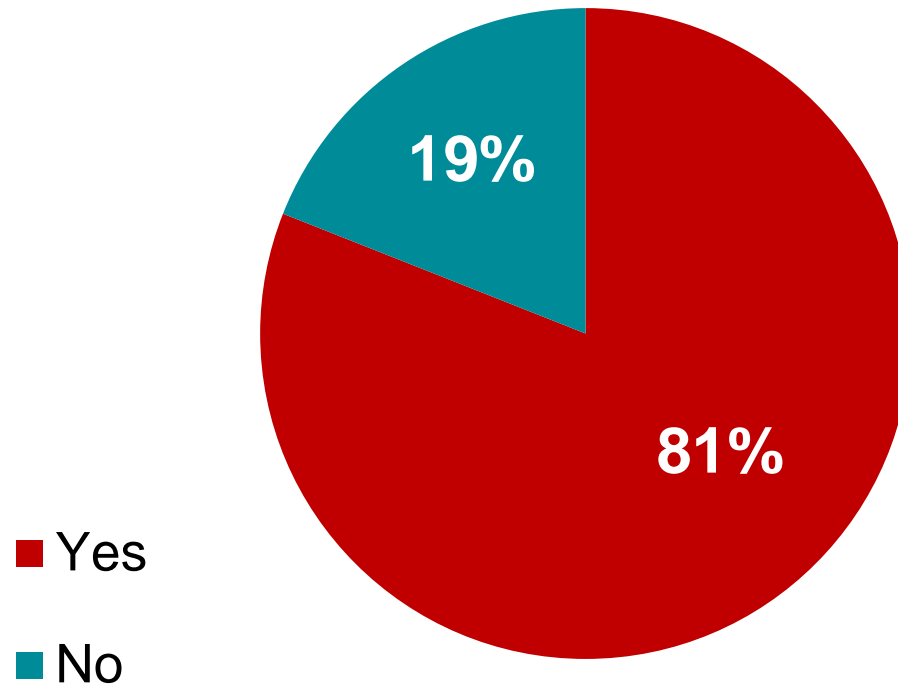
PARENT SURVEY, peanut allergy, N=853

# Some families have had to make career decisions based on FA, leading to negative financial impact on the entire household.



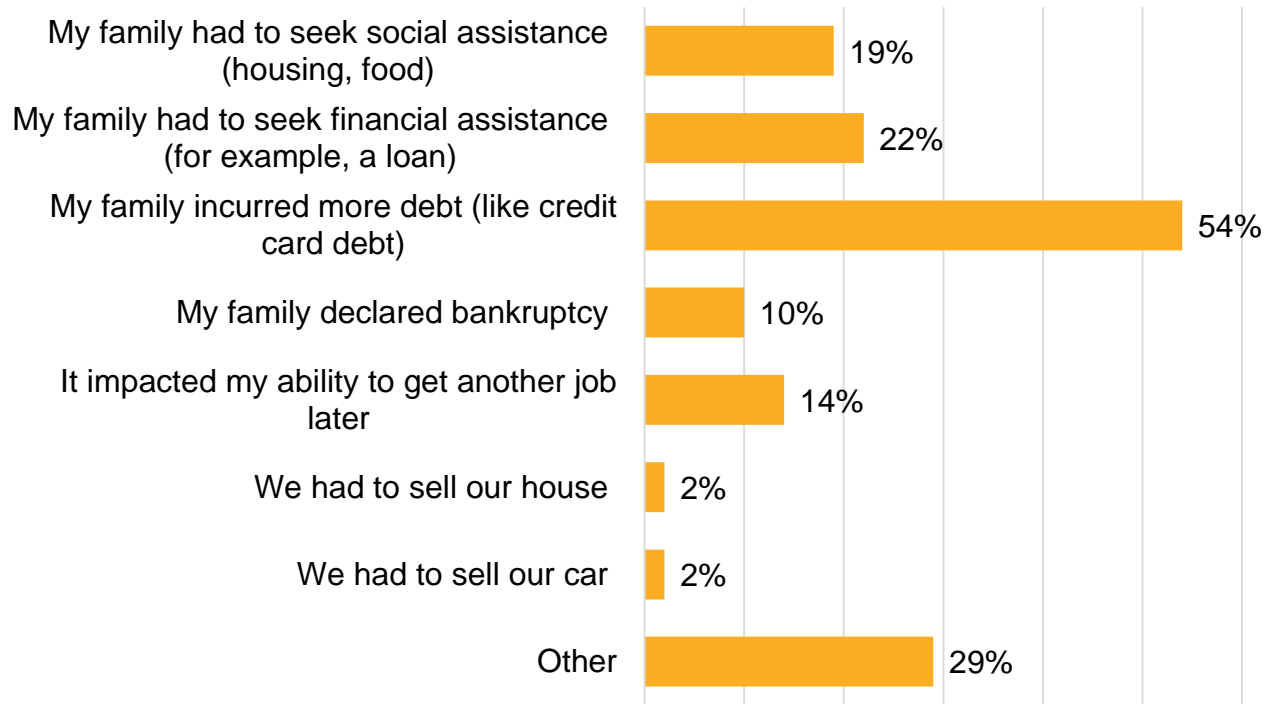
PARENT SURVEY, peanut allergy, N=853

# Did this have a negative impact on your household finances?



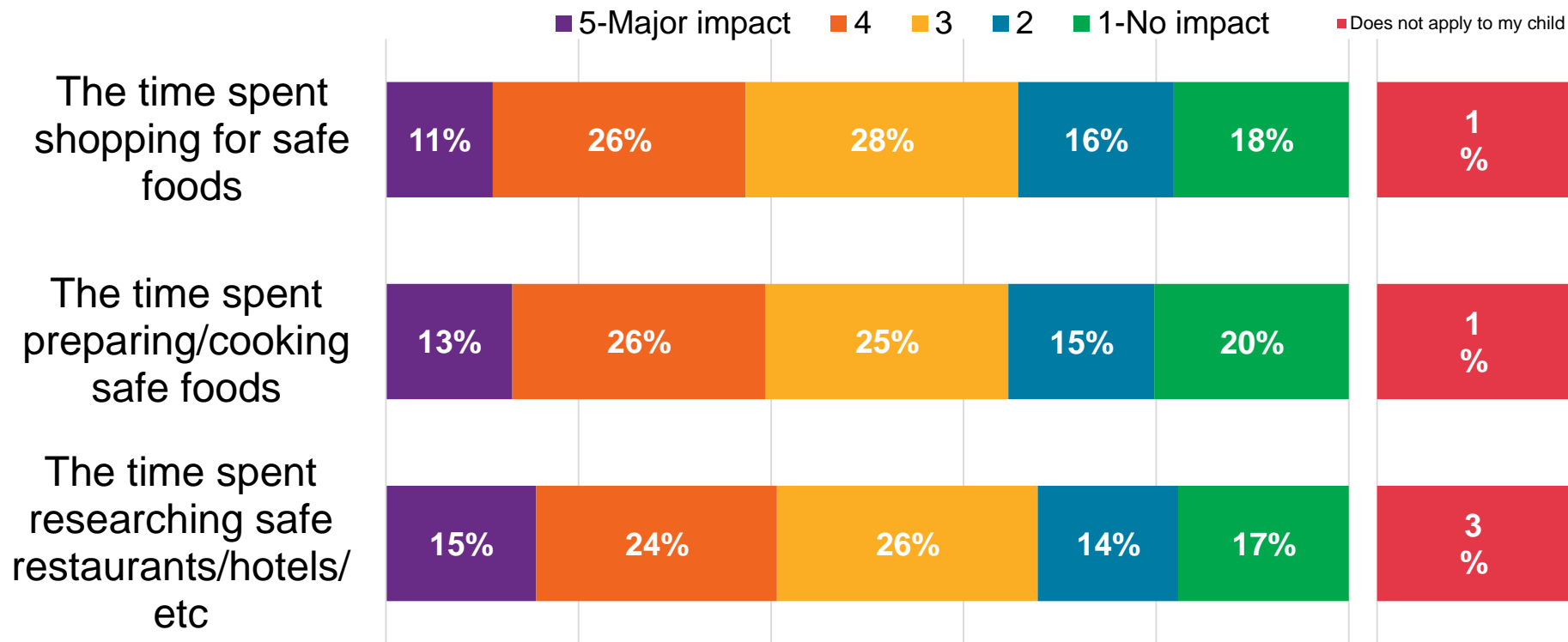
PARENT SURVEY, peanut allergy, N=350, Q41="Yes"

# In what ways?



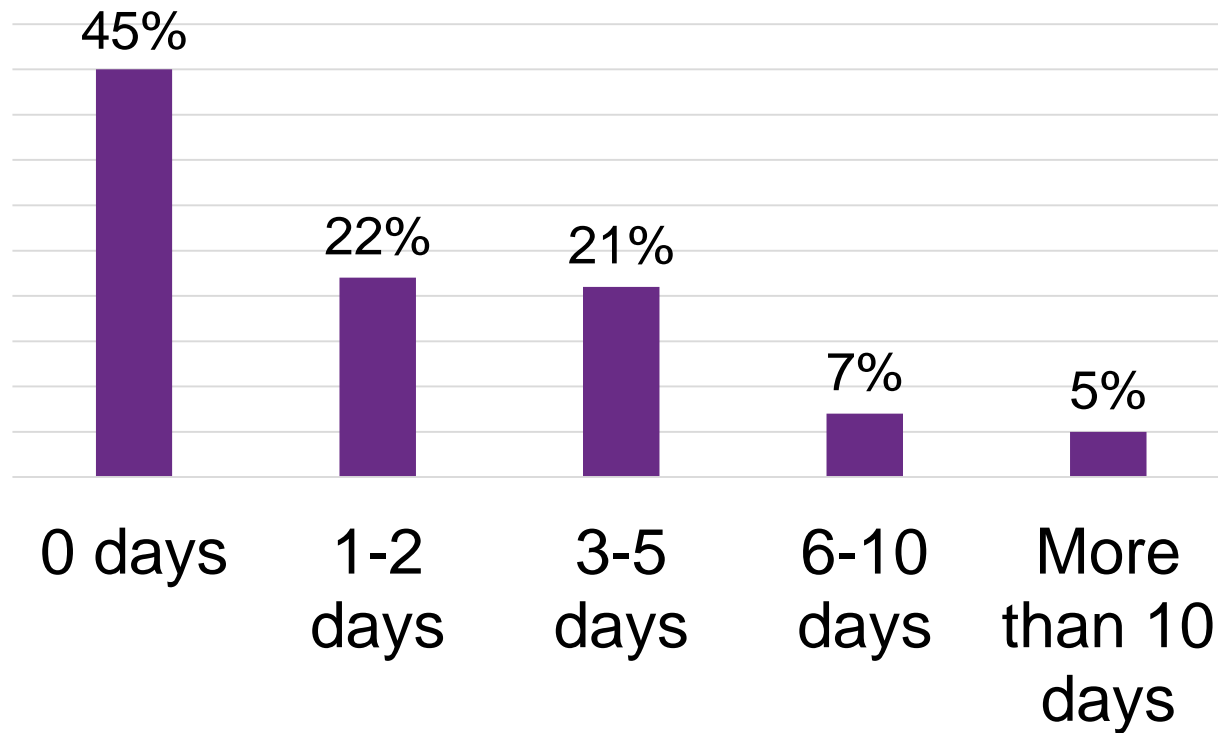
PARENT SURVEY, peanut allergy, N=283, Q42="Yes"

# FA can also present a major time burden for some families



PARENT SURVEY, peanut allergy, N=853

# In the past 12 months, how many days have you missed from work or school due to your child's food allergy?



PARENT SURVEY, peanut allergy, N=853

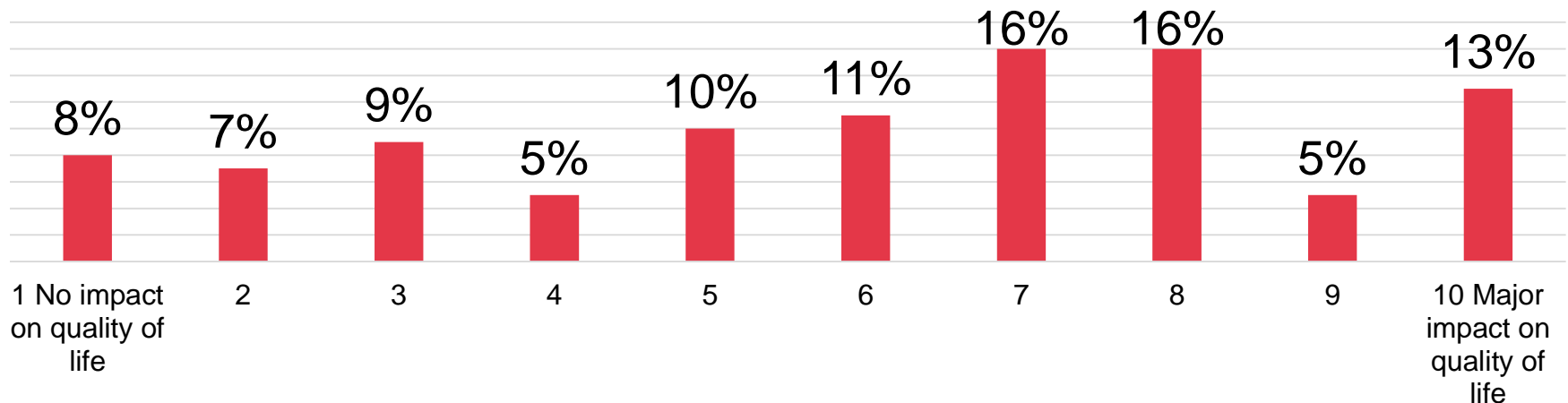
**Many parents of children with PA  
said desensitization and  
tolerance could positively  
impact their child's quality of life**

**Q51. Please answer the following question about your child's quality of life, not your own. Keep in mind their general health, anxiety and their ability to participate in activities at school and outside of school. This can include eating in the lunchroom, field trips, sports, eating at restaurants, eating at friends' houses and travel.**

Think about your child's current quality of life when it comes to their peanut allergy ONLY. Now assume your child could take a treatment that would make them less sensitive to peanuts.

With this treatment, they would have a lower chance of having an allergic reaction. But they would still need to avoid peanuts, carry epinephrine and continue daily treatment. (Assume that the treatment would have a low risk of serious side effects.)

How do you think this type of peanut treatment would affect your child's quality of life?



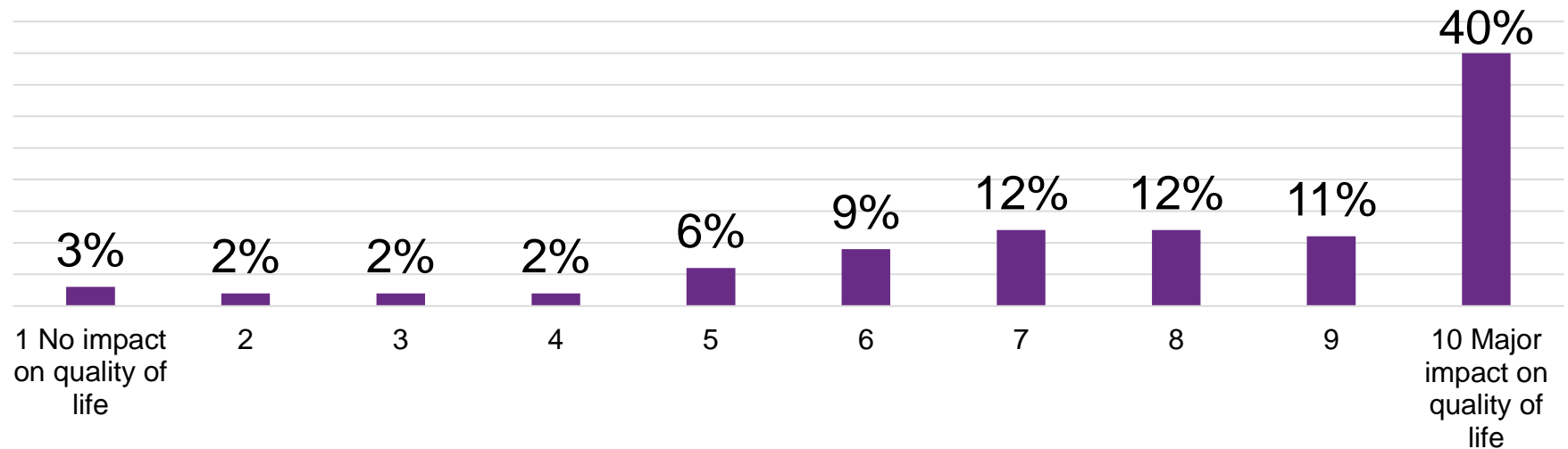
PARENT SURVEY, peanut allergy, N=853



**Q51A. Now, assume your child could take a treatment that would make them tolerant of peanuts.**

**With this treatment, they would no longer need to practice strict avoidance or carry epinephrine. (Assume that the treatment would have a low risk of serious side effects.)**

**How do you think this type of peanut treatment would affect your child's quality of life?**



PARENT SURVEY, peanut allergy, N=853

# IMPLICATIONS: SOCIETAL IMPACT

- Future treatments that may reduce risk of reactions due to accidental exposure may have added benefit on psychosocial well-being of some caregivers.
- Survey results highlight unmet need of caring for the caregiver(s) of children with FA.
- FA may have a larger economic impact on society (with the loss of members of the workforce); more research needed to better quantify/understand economic impact.
- FA impacts many families in ways that are invisible to others; important to look at the whole picture regarding burden of disease and impact on entire family's QoL; need to take concerns of the FA community seriously.

---

# Cost-Effectiveness

**Ryan Hansen, PhD, PharmD**

**Greg Guzauskas, MSPH, PhD**

University of Washington

Department of Pharmacy

Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute



INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW

---

# Disclosures

- Financial support provided to the University of Washington from the Institute for Clinical and Economic Review (ICER).
- The University of Washington researchers report no industry funding related to peanut allergy.

---

# Objective

To estimate the lifetime cost-effectiveness of two peanut allergy immunotherapies, using a decision analytic model.

# Methods in Brief

---

# Overall Approach

- Modeled treatments:
  - AR101 (Aimmune Therapeutics)
  - Viaskin Peanut (DBV Technologies)
- Base case/standard of care comparator: Peanut avoidance alone
- Patients in each comparator are assumed to require lifetime access to epinephrine unless they outgrow their peanut allergy.
- We compared immunotherapies to avoidance alone, not to each other.

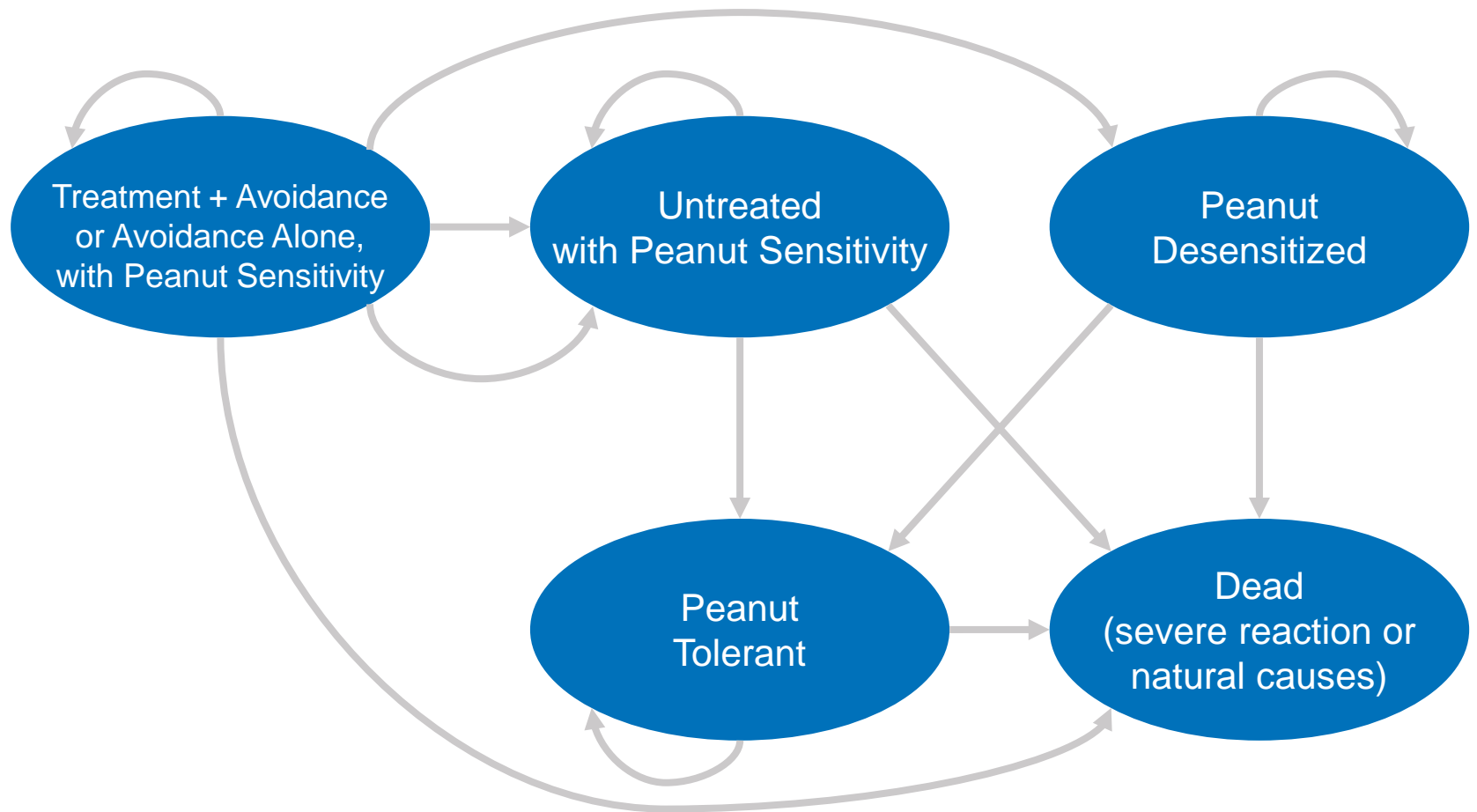
---

# Methods Overview

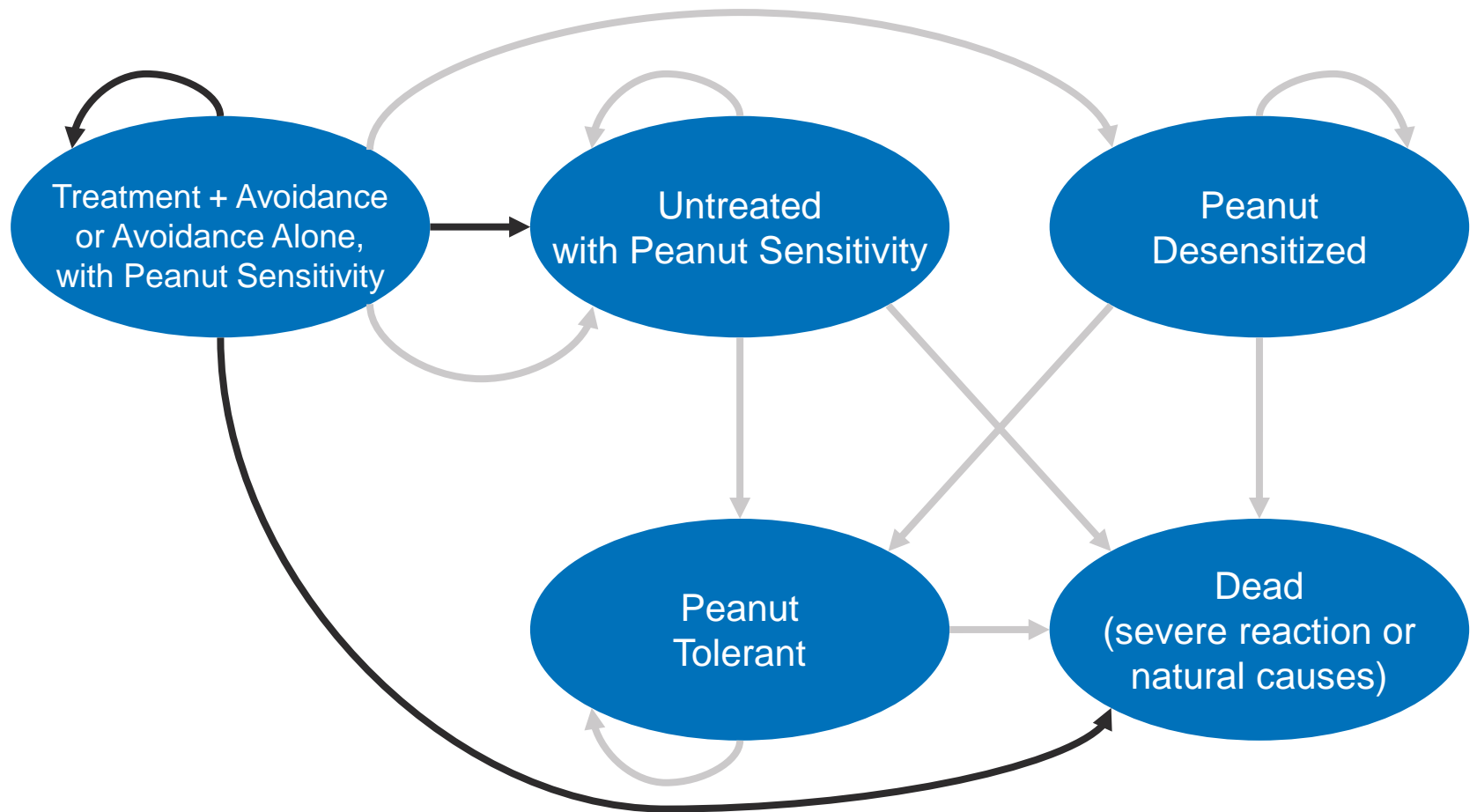
- **Comparisons:** AR101 vs. Avoidance Alone  
Viaskin Peanut vs. Avoidance Alone
- **Population:** Children age 7 with peanut allergy
- **Model:** Markov model
- **Setting:** United States
- **Perspective:** Health care sector
- **Time Horizon:** Lifetime
- **Discount Rate:** 3% per year (costs and outcomes)
- **Cycle Length:** Weekly for year 1 (trial durations), annual thereafter
- **Primary Outcomes:** Lifetime costs  
Quality adjusted life-years gained  
Incremental cost-effectiveness ratios  
(Cost per quality-adjusted life year gained)



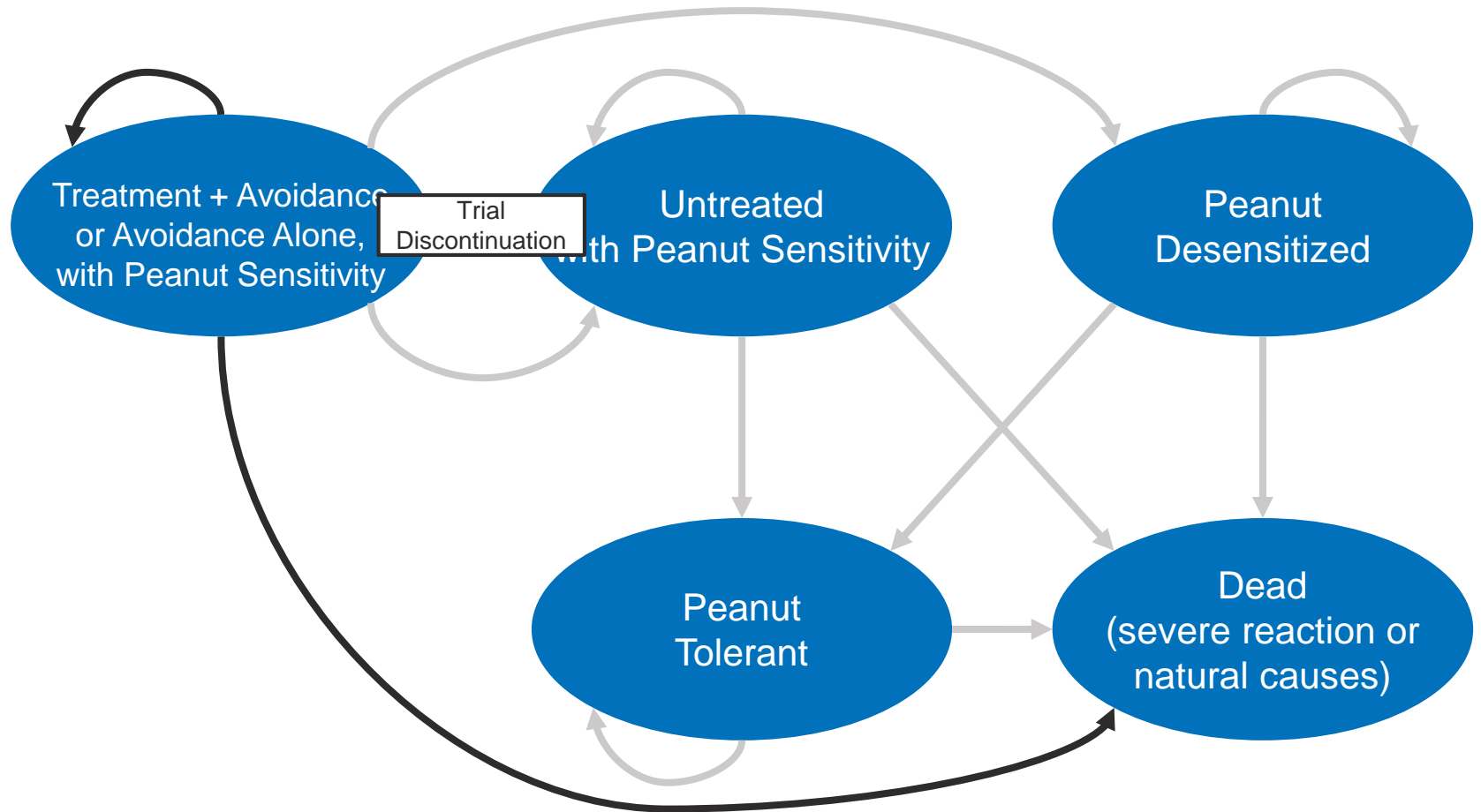
# Model Schematic



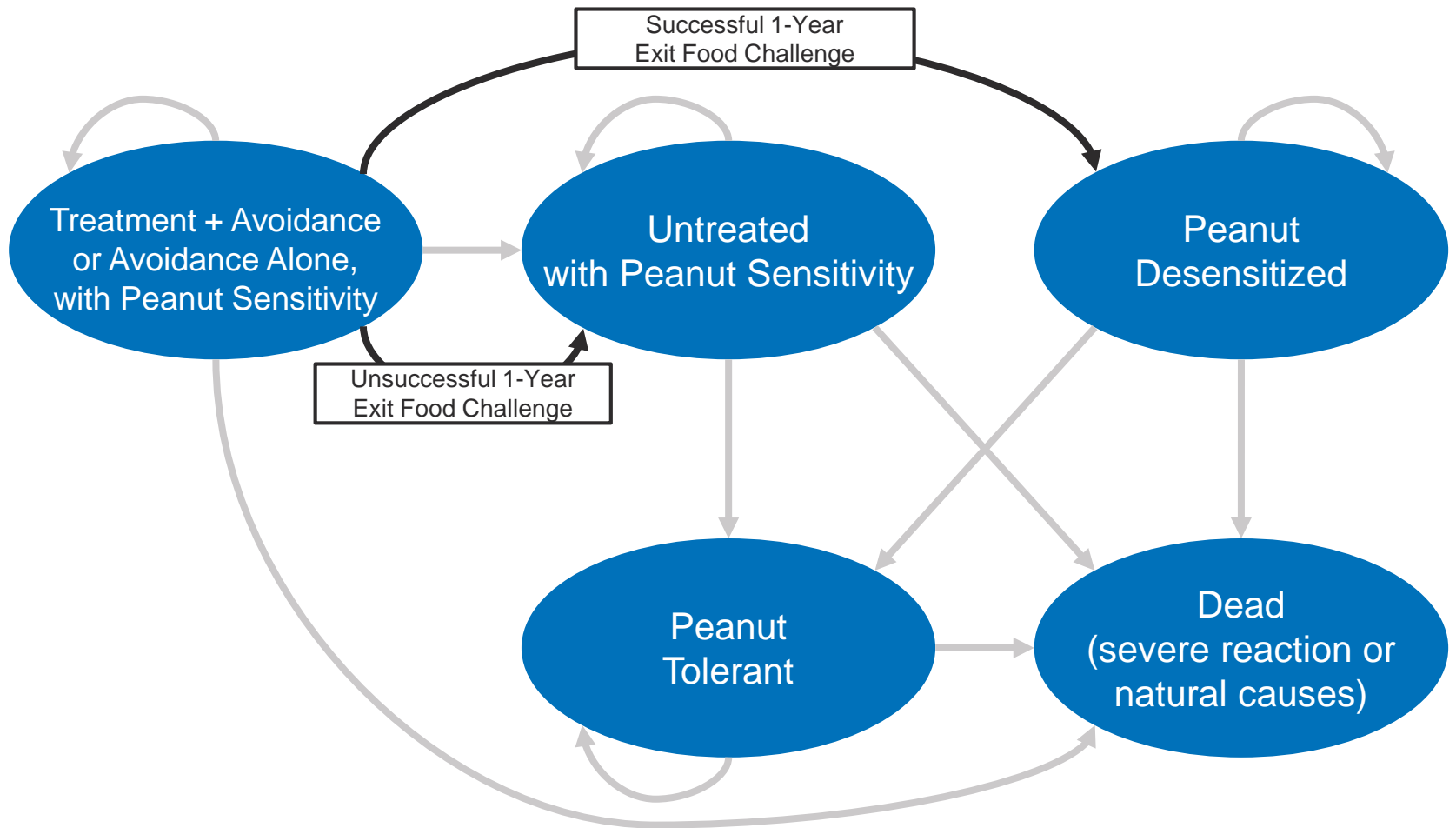
# Model Schematic: Year 1 (Weekly Cycles)



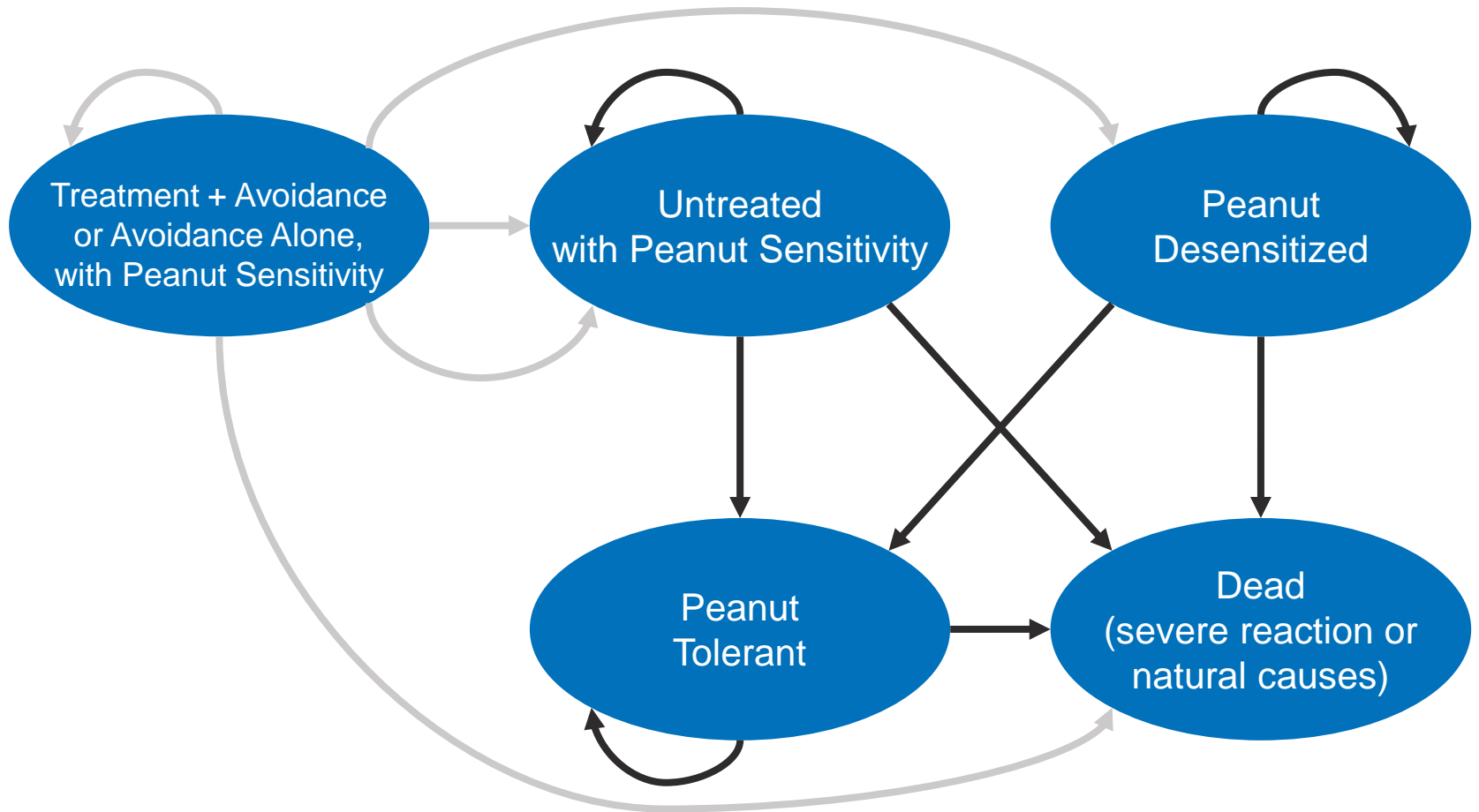
# Model Schematic: Year 1 (Weekly Cycles)



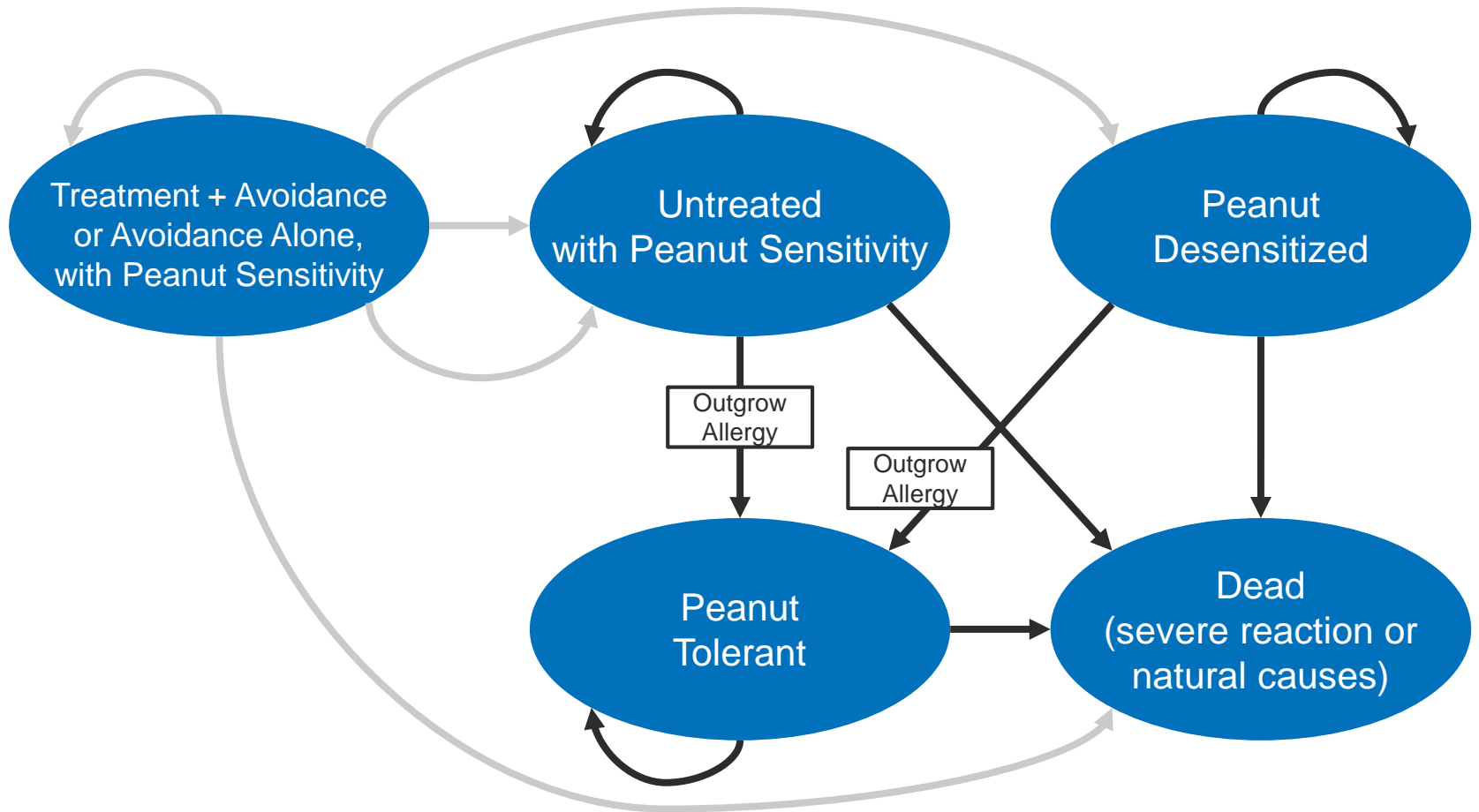
# Model Schematic: End of Year 1



# Model Schematic: Years 2+



# Model Schematic: Years 2+



---

# Key Model Assumptions

- Achievement of desensitization leads to better quality of life.
- Individuals who successfully complete AR101 or Viaskin Peanut trial regimens and pass the 1-year exit food challenge remain on maintenance treatment indefinitely, unless they outgrow their allergy.
- Individuals who pass the 1-year exit food challenge are considered desensitized regardless of treatment arm.
- Individual behavior, e.g., increased risk-taking, does not change based on modeled health states.

# Clinical Inputs: Efficacy vs. Placebo

## Results of PALISADE Trial<sup>1</sup> (AR101)

| Placebo Proportion Tolerating Dose | AR101 Between Group Difference vs. Placebo |
|------------------------------------|--|
| 4.0% (95% CI: 0.6% - 7.5%)         | 63.2% (95% CI: 53.0% - 73.3%)              |

## Results of PEPITES Trial<sup>2</sup> (Viaskin<sup>®</sup> Peanut)

| Placebo Proportion with Treatment Response | Viaskin <sup>®</sup> Peanut Between Group Difference vs. Placebo |
|--|--|
| 13.6% (95% CI: 7.4% - 19.8%)               | 21.7% (95% CI: 12.4% - 29.8%)                                    |



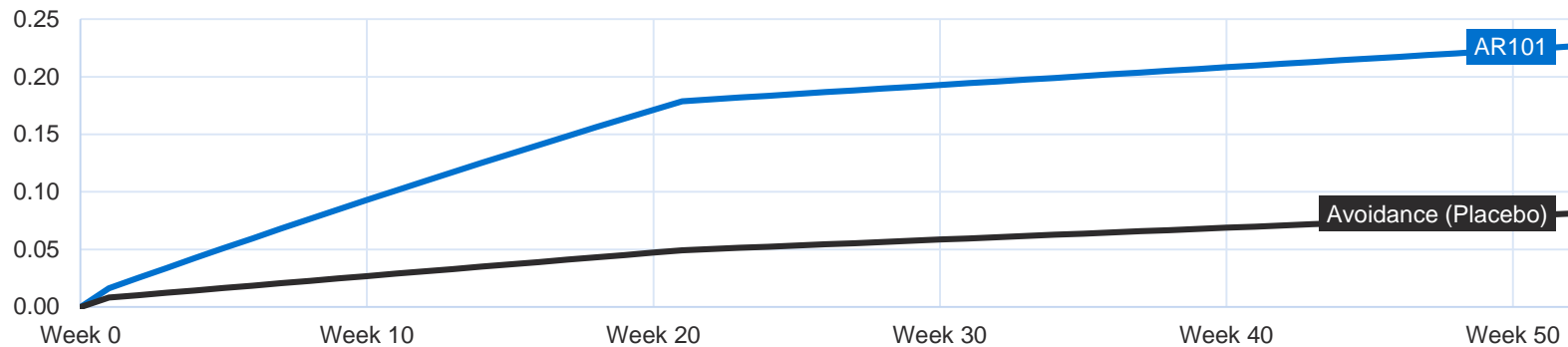
---

# Placeholder Drug Costs Based on Analyst Estimates

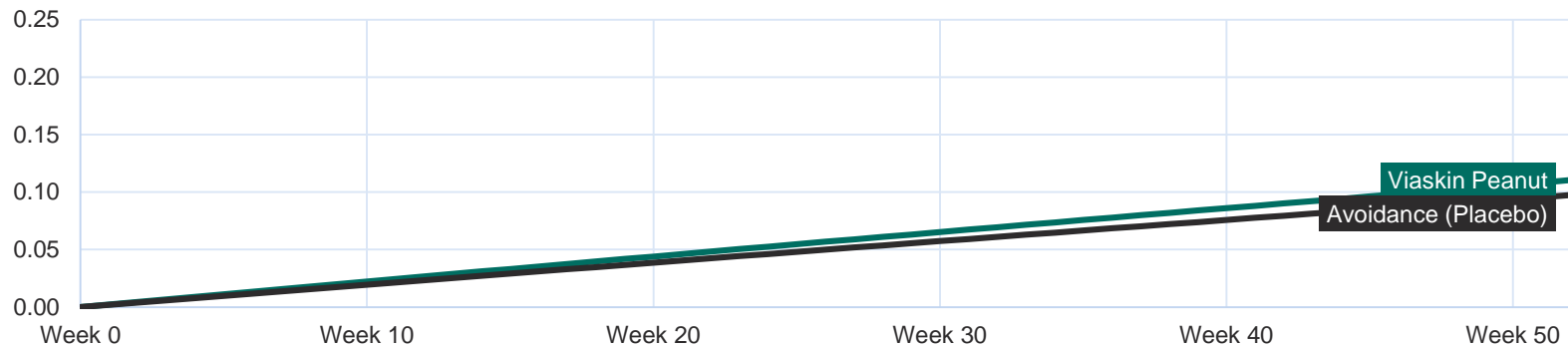
- AR101 placeholder cost of \$4,200 per year<sup>1</sup>
- Viaskin Peanut placeholder cost of \$6,500 per year<sup>1</sup>

# Treatment Discontinuation

Modeled Treatment Discontinuation Based on PALISADE<sup>1</sup>



Modeled Treatment Discontinuation Based on PEPITES<sup>2</sup>

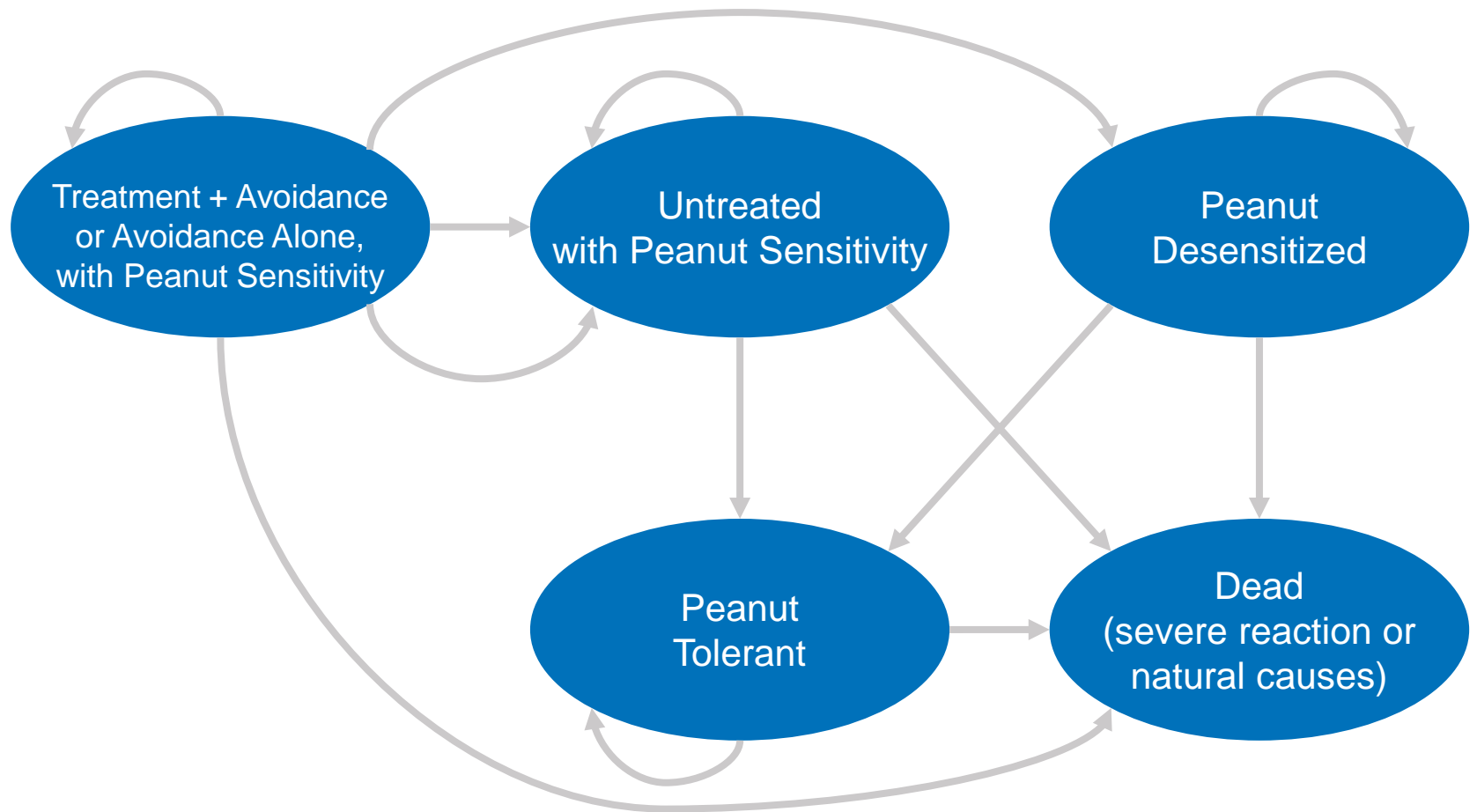


# Adverse Event Costs and Disutilities

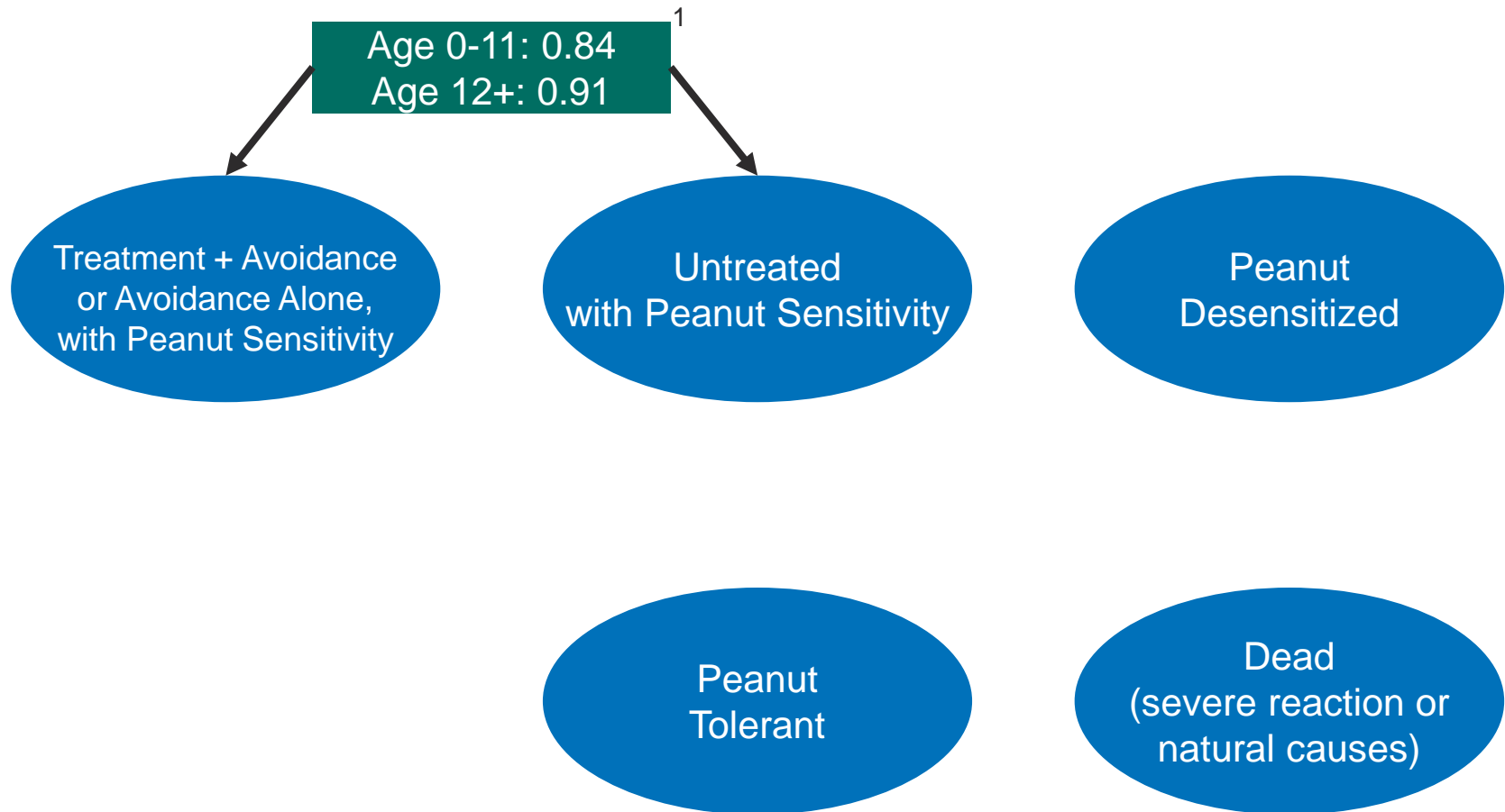
|                            | Serious AE Cost <sup>1</sup> | Serious AE Disutility <sup>2</sup> |
|----------------------------|------------------------------|------------------------------------|
| Anaphylactic Reaction      | \$9,332.46                   | 0.311 for 3 days                   |
| Systemic Allergic Reaction | \$3,535.64                   | 0.311 for 3 days                   |
| Asthma Exacerbation        | \$3,879.02                   | 0.311 for 3 days                   |

Modeled risk reduction in anaphylaxis rate: 95% if desensitized<sup>3</sup>

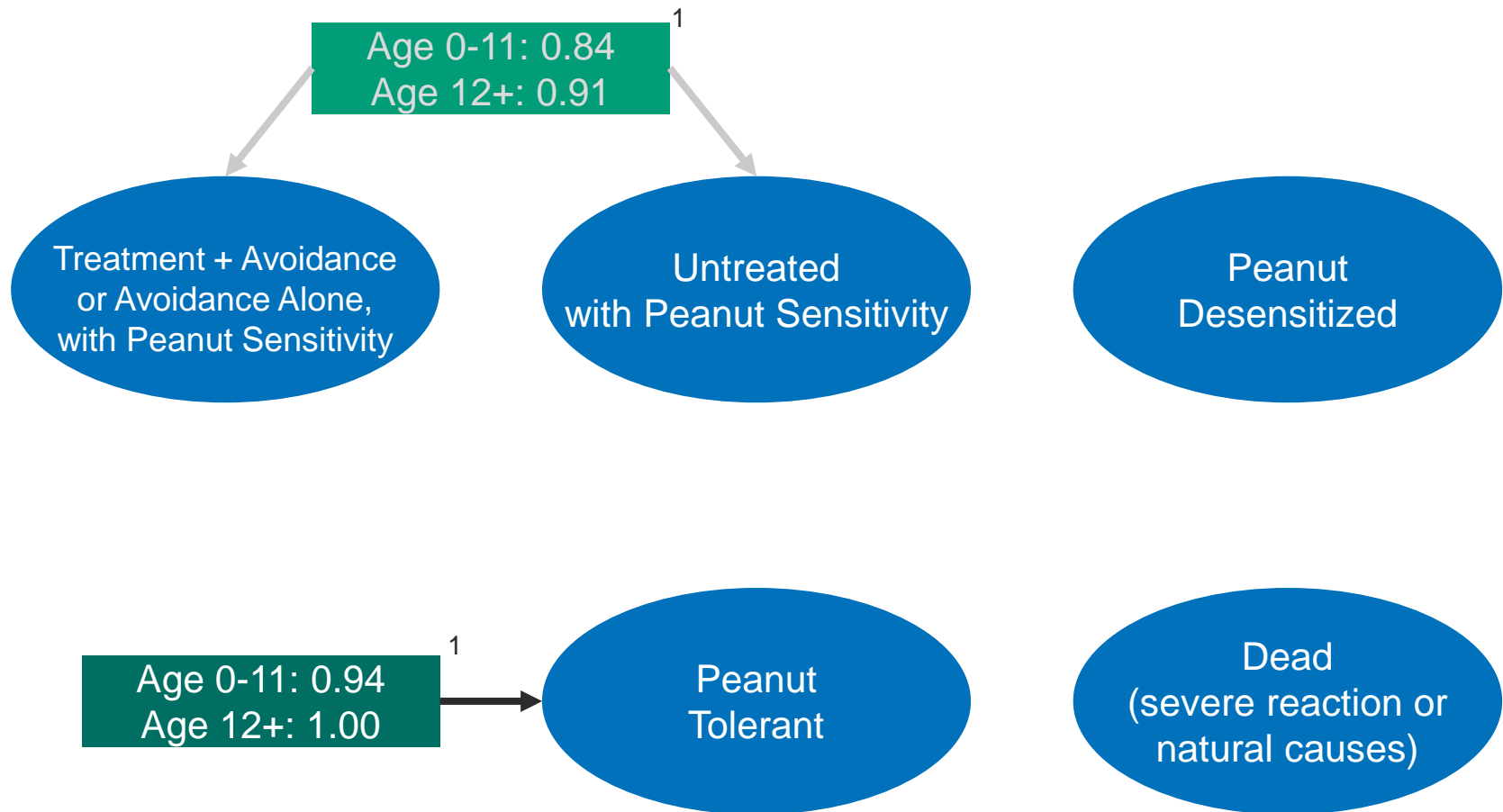
# Health State Utilities



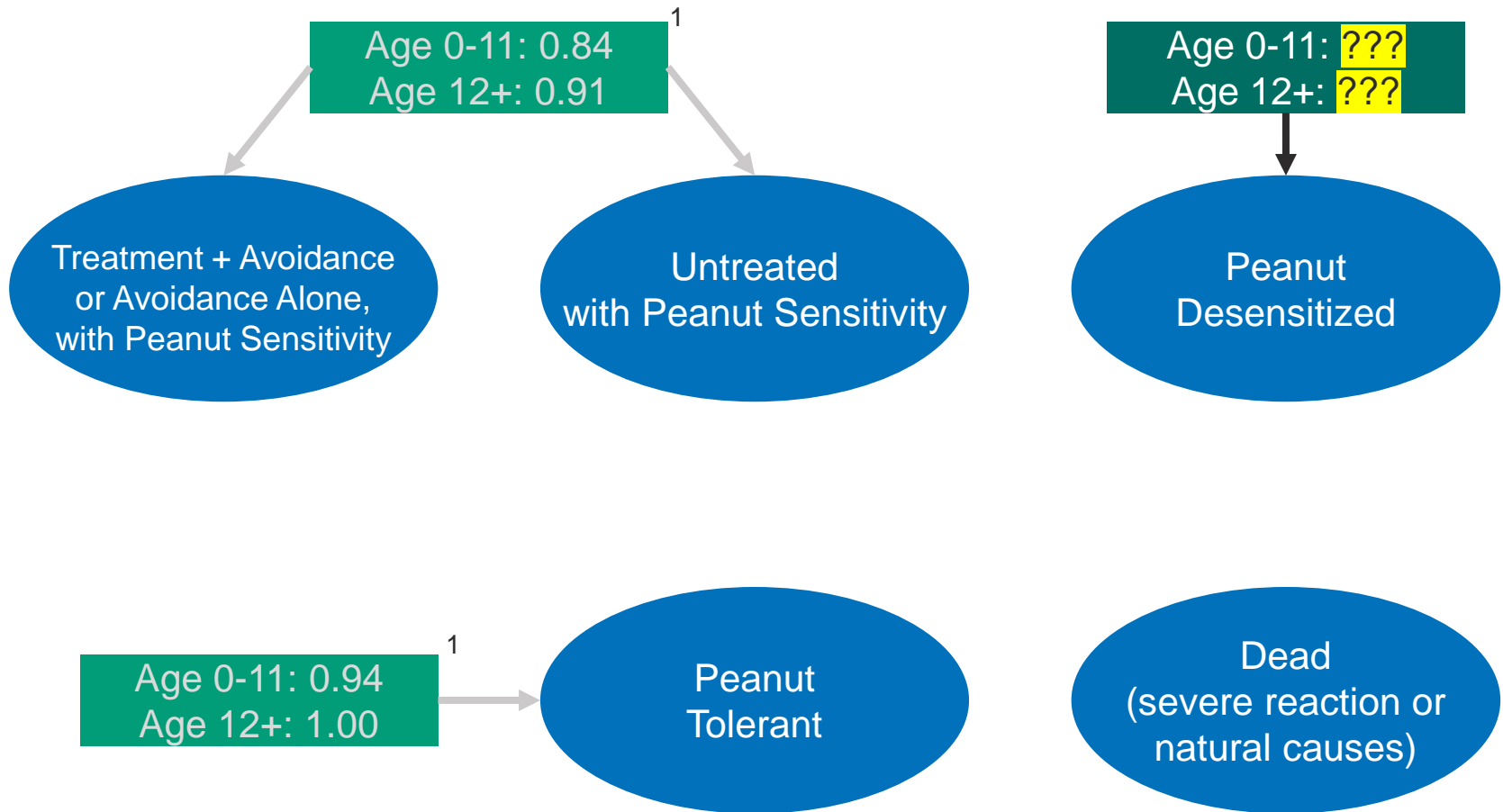
# Health State Utilities



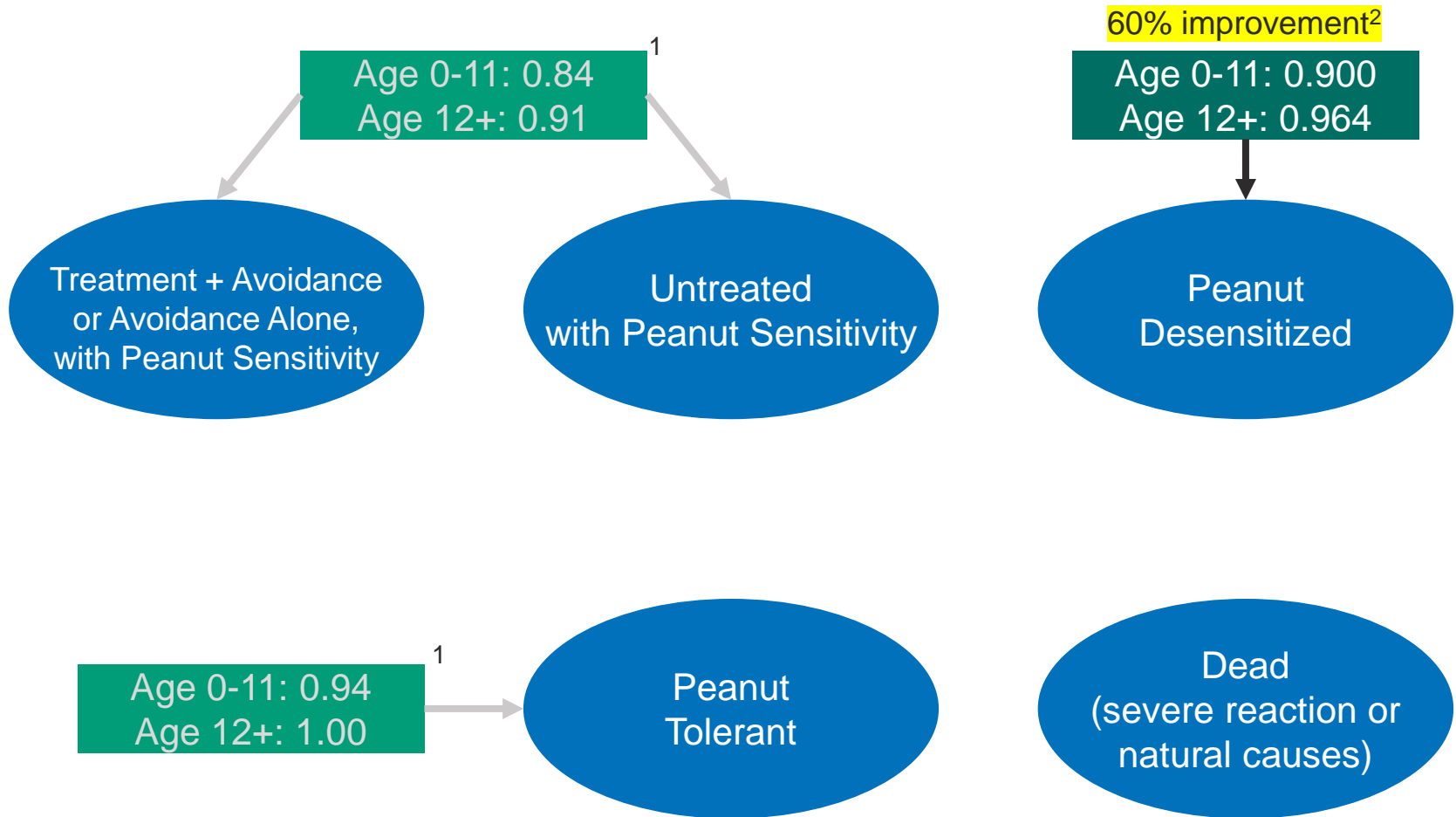
# Health State Utilities



# Health State Utilities



# Health State Utilities





# Parameters Used in Societal Analysis

| Societal Perspective Costs <sup>1</sup> | Cost Estimate  |
|---|----------------|
| Annual Out-of-Pocket Costs              | \$931          |
| Annual Productivity Loss                | \$2,399        |
| <b>Total Annual Cost</b>                | <b>\$3,330</b> |

| Societal Perspective Parent/Caregiver Utilities                       | Utility Estimate |
|---|------------------|
| Treatment or Avoidance Alone with Peanut Sensitivity*                 | 0.851 to 0.891   |
| Treatment or Avoidance Alone with Peanut Desensitization <sup>2</sup> | 0.881 to 0.897   |
| Peanut Tolerant <sup>3</sup>  | 0.901            |

\*Assumption: disutility range 0.01 to 0.05 subtracted from utility estimate for peanut tolerant

# Results

# Lifetime Outcomes and Value-Based Prices: AR101 vs. Avoidance Alone

| Treatment       | QALYs       | Life Years  | VBP at \$50,000/QALY | VBP at \$100,000/QALY | VBP at \$150,000/QALY |
|-----------------|-------------|-------------|----------------------|-----------------------|-----------------------|
| AR101           | 27.19       | 28.69       | <b>\$2,369</b>       | <b>\$4,808</b>        | <b>\$7,248</b>        |
| Avoidance Alone | 26.44       | 28.69       |                      |                       |                       |
| Incremental     | <b>0.75</b> | <b>0.00</b> |                      |                       |                       |

VBP: value-based price per year

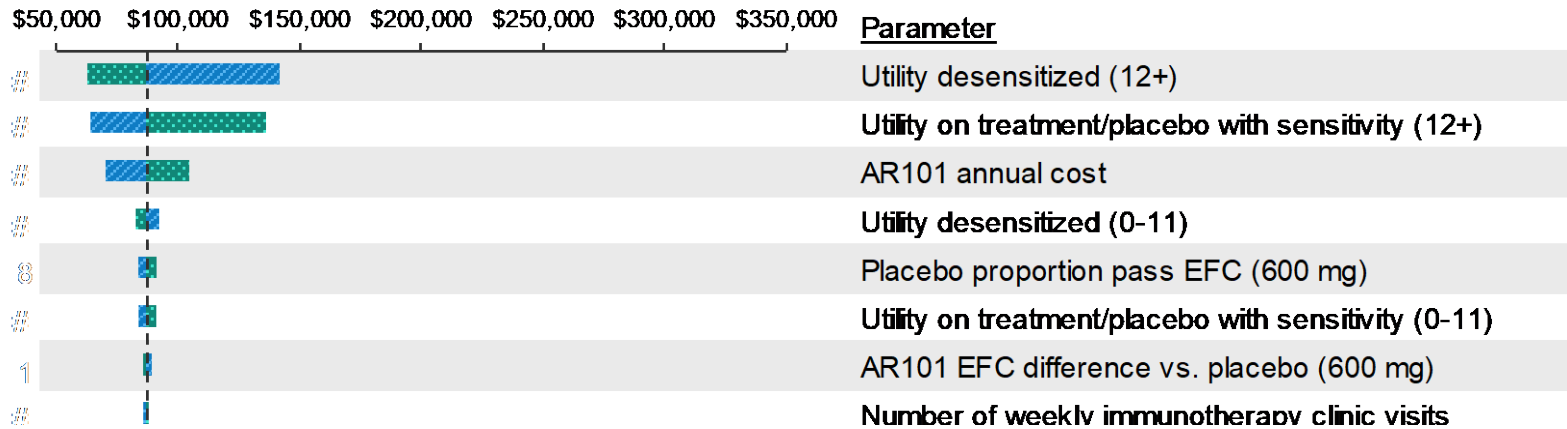
# Lifetime Outcomes and Value-Based Prices: Viaskin Peanut vs. Avoidance Alone

| Treatment       | QALYs       | Life Years  | VBP at \$50,000/QALY | VBP at \$100,000/QALY | VBP at \$150,000/QALY |
|-----------------|-------------|-------------|----------------------|-----------------------|-----------------------|
| Viaskin Peanut  | 26.81       | 28.69       | <b>\$1,508</b>       | <b>\$3,010</b>        | <b>\$4,513</b>        |
| Avoidance Alone | 26.55       | 28.69       |                      |                       |                       |
| Incremental     | <b>0.26</b> | <b>0.00</b> |                      |                       |                       |

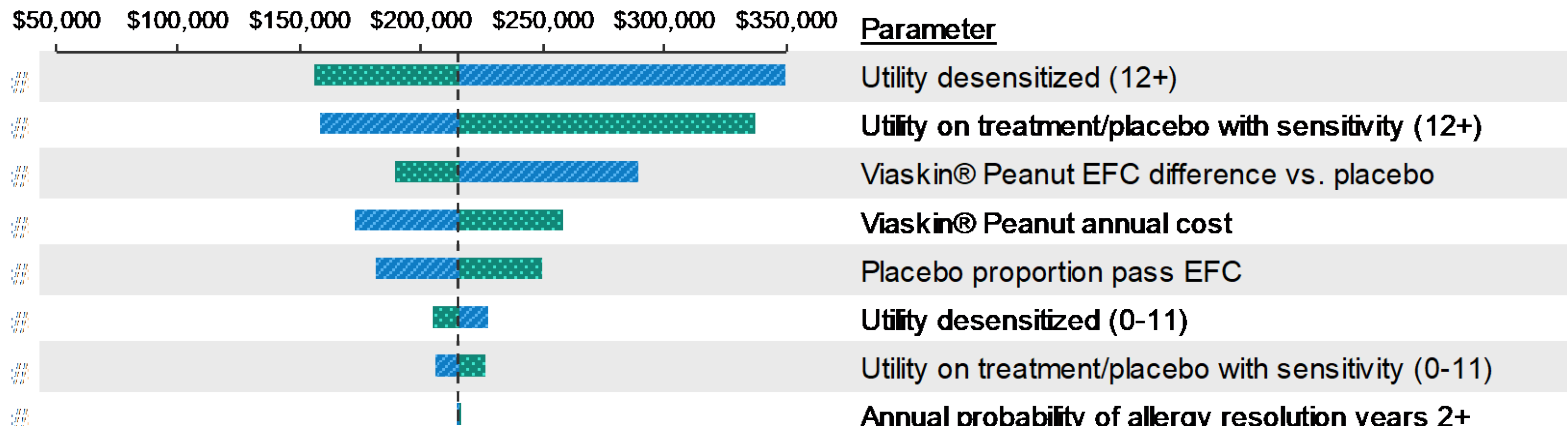
VBP: value-based price per year

# One-Way Sensitivity Analyses

## AR101 vs. Avoidance



## Viaskin Peanut vs. Avoidance



---

# Scenario Analyses

Incremental cost-effectiveness ratios were generally stable (no meaningful changes) when we:

- Extended treatment discontinuation rates beyond trial duration
- Turned off probability of spontaneous tolerance
- Varied risk of accidental peanut exposure
- Varied patient age of model entry
- Employed PALISADE secondary outcomes (AR101)
- Varied epinephrine utilization  $\pm 50\%$  in years 2+

---

# Modified Societal Perspective Analysis

- Adding societal costs only:
  - Reduced the incremental cost
  - Reduced the incremental cost-effectiveness ratios
  - Increased the value-based price/year
    - AR101: \$5,300 to \$10,200
    - Viaskin Peanut: \$3,300 to \$6,400
- Adding parent/caregiver utilities:
  - Increased the incremental QALYs
  - Further reduced the incremental cost-effectiveness ratios
  - Further increased the value-based price/year
    - AR101: \$6,100 to \$12,600
    - Viaskin Peanut: \$3,800 to \$7,800

---

# Limitations

- The utility estimates used for the base-case model come from a food allergy, but not necessarily peanut allergy, patient population.
- Our assumption of a 60% utility improvement for desensitization is optimistic, and could be questioned.
- We lacked any long-term treatment data to inform decisions such as the duration of treatment.
- We had no data to tie desensitization to patient outcomes, such as a lifetime reduction in reactions due to accidental exposure.



---

# Comments Received

- Utilities and our assumption for desensitization
- Immunotherapy placeholder costs should be the same
- Clarification on number of clinical visits for AR101 provided through model sharing agreement

---

# Summary

- More costly, more effective, unknown cost-effectiveness: Immunotherapies for peanut allergy appear to provide benefit to patients and parents/caregivers versus avoidance, but their cost-effectiveness will depend on their cost.
- Results were sensitive to the utility values and immunotherapy costs.

# **Manufacturer Public Comment and Discussion**

---

# Speakers

| Name               | Title   | Company                 |
|--------------------|---|-------------------------|
| Todd Green, MD     | Vice President Medical Affairs<br>North America | DBV Technologies        |
| Stephen Tilles, MD | Senior Director of Medical<br>Affairs           | Aimmune<br>Therapeutics |

# Public Comment and Discussion

---

# Charmayne Anderson, MPA

Director of Advocacy, Allergy & Asthma Network (AAN)

## *Conflicts of interest:*

- Allergy & Asthma Network has accepted contributions from DBV Technologies and Aimmune Therapeutics for unbranded disease education and awareness in 2018-2019.

---

## Nurry Hong

Chief of Strategy and Innovation, Food Allergy Research & Education (FARE)

### *Conflicts of interest:*

- FARE has received general support grants or corporate sponsorship from each of DBV Technologies and Aimmune Therapeutics. These general support grants/sponsorships are charitable in nature and do not require FARE to perform any service for or on behalf of either DBV or Aimmune. At one time FARE was a shareholder of Aimmune, but those shares were sold in their entirety in 2016.

---

## Kenneth Mendez, MBA

President and CEO, Asthma and Allergy Foundation of America (AAFA)

### *Conflicts of interest:*

- The AAFA receives greater than 25% of its funding to produce educational materials and for patient research through grants from pharmaceutical companies.



---

# Kari Nadeau, MD, PhD

Professor of Medicine and Pediatrics, Stanford University

## *Conflicts of interest:*

- Dr. Nadeau has participated in sponsored research for clinical studies from Aimmune Therapeutics, DBV Technologies, AnaptysBio, Astellas, Novartis, Regeneron, Adare, Sanofi, and Stallergenes-Greer.
- Dr. Nadeau serves as part of NIAID CoFAR, NIAID Immune Tolerance Network, and NHLBI Data and Safety Monitoring Board.

---

# Tessa Grosso

Patient Advocate and Student

## *Conflicts of interest:*

- None disclosed.

**Lunch**

**Meeting will resume at 1:00 pm**

---

# Oral Immunotherapy and Viaskin<sup>®</sup> Peanut for Peanut Allergy: Effectiveness and Value

Public Meeting – June 11, 2019



INSTITUTE FOR CLINICAL  
AND ECONOMIC REVIEW

WIFI: TCEGuest

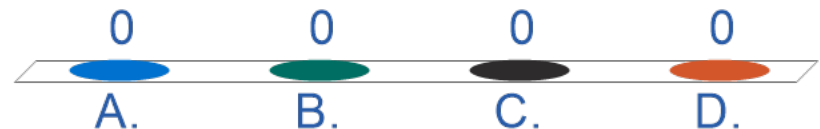
# Voting Questions

WIFI: TCEGuest

---

## The Bay Area is well known for which important event in aviation history?

- A. The first air transport company opened in San Francisco in 1897.
- B. Amelia Earhart became the first person to do a solo flight across the Pacific, from Honolulu to Oakland.
- C. The first free-fall parachute jump at Oakland military base.
- D. The Wright brothers suffered from their first airplane crash (1908), killing one passenger on board.



---

## Patient Populations for Questions

- **AR101:** Children between the ages of four and 17 years with peanut allergy.
- **Viaskin Peanut:** Children between the ages of four and 11 years with peanut allergy.

---

**1. Is the evidence adequate to demonstrate that the net health benefit of AR101 plus strict peanut avoidance is superior to continued avoidance alone?**

- A. Yes
- B. No



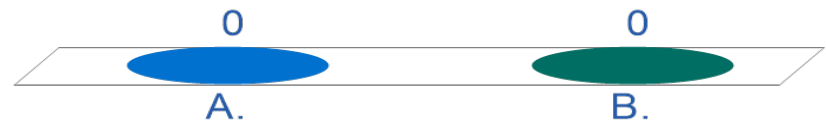


---

**2. Is the evidence adequate to demonstrate that the net health benefit of Viaskin Peanut plus strict peanut avoidance is superior to continued avoidance alone?**

A. Yes

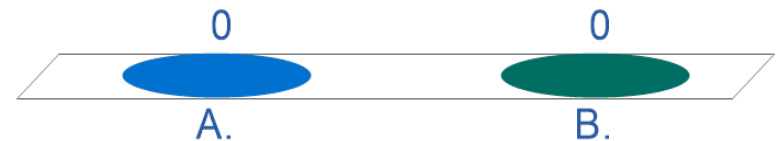
B. No



---

### 3. Is the evidence adequate to distinguish the net health benefit of AR101 and Viaskin Peanut?

- A. Yes
- B. No



---

**3a. If the answer to Q3 is Yes:**

**Based on the available evidence, which therapy has greater net health benefit: (a) AR101 plus strict peanut avoidance, or (b) Viaskin Peanut plus strict peanut avoidance?**

A. AR101

B. Viaskin Peanut



---

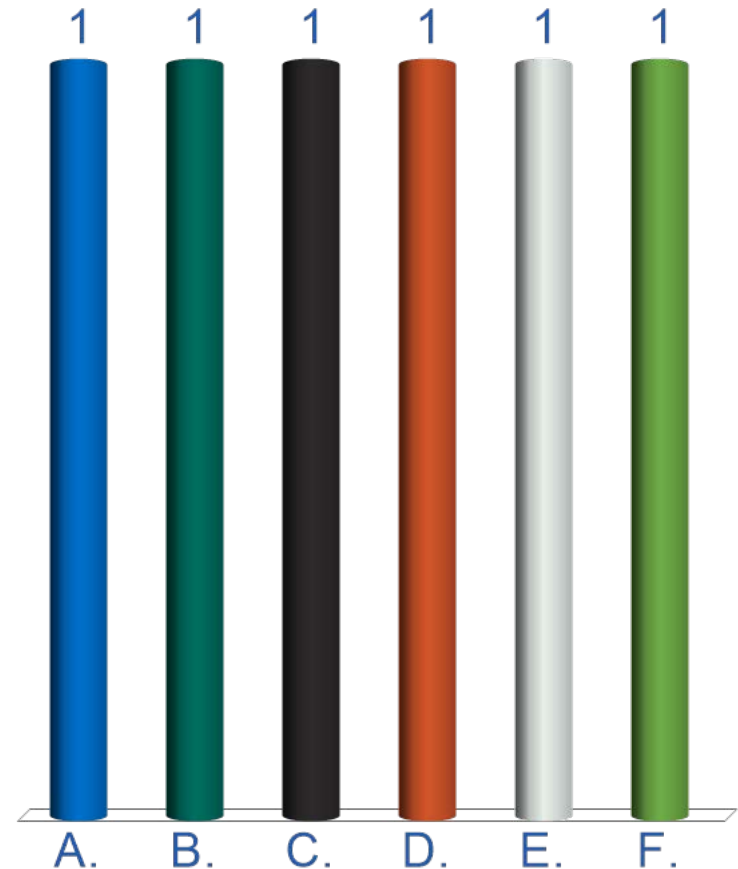
**4. Is the evidence adequate to demonstrate that the net health benefit of AR101 is superior to oral immunotherapy as practiced currently?**

- A. Yes
- B. No



## 5. Does desensitizing patients with Viaskin Peanut offer one or more of the following potential “other benefits” in comparison to strict peanut avoidance alone? (select all that apply)

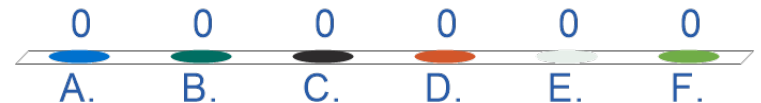
- A. Reduces important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
- B. Significantly reduces caregiver or broader family burden.
- C. Offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
- D. Will have a significant impact on improving patients’ ability to return to work, school, and/or their overall productivity.
- E. There are other important benefits or disadvantages that should have an important role in judgments of the value of Viaskin Peanut:  
\_\_\_\_\_



---

## 6. Does desensitizing patients with AR101 offer one or more of the following potential “other benefits” in comparison to strict peanut avoidance alone? (select all that apply)

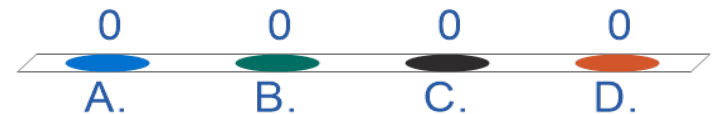
- A. Reduces important health disparities across racial, ethnic, gender, socioeconomic, or regional categories.
- B. Significantly reduces caregiver or broader family burden.
- C. Offers a novel mechanism of action or approach that will allow successful treatment of many patients for whom other available treatments have failed.
- D. Will have a significant impact on improving patients’ ability to return to work, school, and/or their overall productivity.
- E. There are other important benefits or disadvantages that should have an important role in judgments of the value of AR101: \_\_\_\_\_.



---

## 7. Are any of the following contextual considerations important in assessing the long-term value for money for Viaskin Peanut in comparison to strict peanut-avoidance alone? (select all that apply)

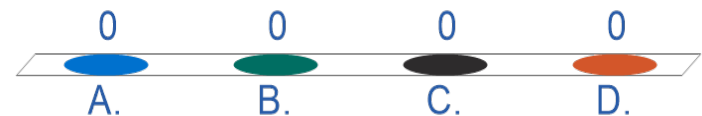
- A. Intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
- B. Significant uncertainty about the long-term risk of serious side effects of this intervention.
- C. Significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
- D. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: \_\_\_\_\_.



---

## 8. Are any of the following contextual considerations important in assessing the long-term value for money for AR101? (select all that apply)

- A. Intended for the care of individuals with a condition of particularly high severity in terms of impact on length of life and/or quality of life.
- B. Significant uncertainty about the long-term risk of serious side effects of this intervention.
- C. Significant uncertainty about the magnitude or durability of the long-term benefits of this intervention.
- D. There are additional contextual considerations that should have an important role in judgments of the value of this intervention: \_\_\_\_\_.





**Break**

**Meeting will resume in 15 minutes**

# Policy Roundtable

# Policy Roundtable Participants

| Name   | Title  | COI Declaration   |
|--|--|---|
| <b>Todd Green, MD, FAAAAI</b>                    | Vice President Medical Affairs North America, DBV Technologies; Clinical Associate Professor of Pediatrics, UPMC Children's Hospital of Pittsburgh | Employee of DBV Technologies.   |
| <b>Matthew Greenhawt, MD</b>                     | Director, Food Challenge and Research Unit, Children's Hospital Colorado   | Consulted for Aimmune Therapeutics and received honorarium as a board member for Aimmune Therapeutics and DBV Technologies. |
| <b>Ruchi S. Gupta, MD, MPH</b>                   | Professor of Pediatrics and Medicine, Northwestern University Feinberg School of Medicine; Director, Center for Food Allergy & Asthma Research     | Received grants from Aimmune Therapeutics and served as a medical consultant for DBV Technologies and Aimmune Therapeutics. |
| <b>Nurry Hong</b>                                | Chief of Strategy and Innovation, Food Allergy Research & Education  | FARE receives financial support from multiple sources, including DBV Technologies and Aimmune Therapeutics.                 |
| <b>Caroline Moassessi</b>                        | Patient Advocate   | None disclosed.   |
| <b>Stephen Tilles, MD</b>                        | Senior Director of Medical Affairs, Aimmune Therapeutics   | Employee of Aimmune Therapeutics.   |
| <b>John S. Yao, MD, MPH, MBA, MPP, CPC, FACP</b> | Regional Vice President and Chief Medical Officer, Anthem Blue Cross   | Employee of Anthem Blue Cross.  |

# Reflections from CTAF

---

## Next Steps

- Meeting recording posted to ICER website next week
- Final Report published before July 10
  - Includes description of CTAF votes, deliberation; policy roundtable discussion
- Materials available at <https://icer-review.org/topic/peanut-allergy/>

**Adjourn**