

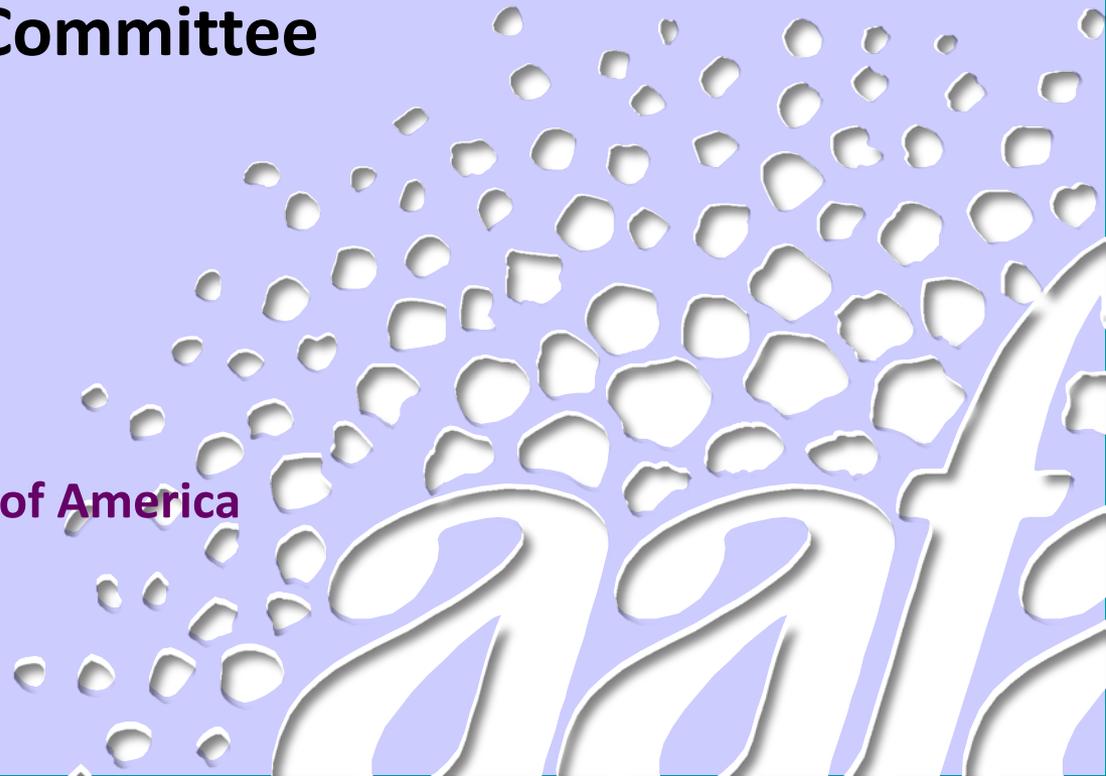


Asthma and Allergy
Foundation of America

The Patient Perspective on Evaluation of Allergenic Products

Comments to the FDA Allergenic Products Advisory Committee

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ABOUT THE ASTHMA AND ALLERGY FOUNDATION OF AMERICA (AAFA)

- **More than 60 years of service to the millions of Americans with asthma and allergic disease**
- **Our mission: to improve their lives through education, advocacy and research**
- **Our perspective: If we truly aspire to “patient-centered care,” the patient’s voice needs to be drive change in healthcare**
- **Our goal: to bring the voice of patients with asthma and allergic disease—with high fidelity and with force—to the conversations that are shaping and re-shaping healthcare**



LIVING WITH ALLERGIES: A PATIENT'S PERSPECTIVE

- **Food allergies – strict avoidance, constant communication and preparation**
 - Every snack and meal
 - No 'safe amount'
- **Allergic rhinitis and asthma**
 - Poor sleep
 - Missed work and school
 - Frequent physician visits
 - Restricted activities

PATIENTS WANT THERAPIES THAT ARE SAFE AND EFFECTIVE

- **Safety is critically important to families with food allergy**
 - **Need to test food allergy therapies in a double-blinded and controlled environment**
- **“Effectiveness” means symptom control/quality of life enhancement/improvements in functional status**
 - **Outcome measures must address the issues that matter to patients**
 - **Endpoints must represent changes that are significant to patients**
- **“Effectiveness” means “it works in the real world”**
 - **Appropriate control may be “standard of care” (not placebo)**
 - **Need for “real world evidence” as well as clinical trials**

THERE ARE OTHER—IMPORTANT—OPPORTUNITIES TO IMPROVE CARE

- **There are gaps—some have said a chasm—between what we KNOW and what we DO**
- **Closing these gaps can have a huge impact on the lives of patients with food and inhalant allergies**
- **The FDA may have an opportunity to advance our understanding—for example, on issues that relate to “how can we get patients more consistently to USE the medications that are safe and effective?”**

WE WANT TO HELP!!!

- **AAFA has a robust online community of families of “Kids with Food Allergies”—and is building this out**
 - A resource for input on clinical trials outcomes and endpoints
 - A resource for clinical trials recruitment
- **AAFA is—with support from PCORI—building a curriculum to educate patients about research**
 - An opportunity to build patient capacity for this Committee (and the FDA)
 - An opportunity to raise patient awareness of this Committee’s work (and of the FDA’s)
- **AAFA is eager to learn how we can collaborate with this Committee (and the FDA) to advance both the basic and the translational science needed to improve the lives of those we serve**

FOR MORE INFORMATION

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