STATEMENT OF FARE (Food Allergy Research and Education) before the Oregon Health Authority's Drug Use Review / Pharmacy and Therapeutics (P&T) Committee August 1, 2024

Position: Approve Xolair and edit approval criteria #14 to remove double-blind placebo-controlled oral food challenge

Dear Members of the Pharmacy and Therapeutics Committee:

FARE (Food Allergy Research and Education), the nation's leading non-profit organization engaged in food allergy advocacy and the largest private funder of food allergy research, strongly supports the Committee approving the use of Xolair to help protect the state's more than 430,000 residents with potentially life-threatening food allergies.

According to 2023 census data and studies published in 2018 and 2019, Oregon's food allergy population is larger than the combined populations of Eugene, Salem, and Springfield as more than 10% of the state's residents have a food allergy. Furthermore, of the 430,000+ residents with food allergies, more than 63,000 are children 18 and under, a population that is larger than Corvallis.

Life-threatening food allergies are on the rise as the Centers for Disease Control and Prevention (CDC) found that over the past 20 years, the rates of children with food allergies has grown by 50% and for children with a peanut or tree nut allergy, it has tripled. Life-threatening food allergies and the risk of fatal anaphylaxis are growing at an even faster rate among African-American, Latino, and Asian-American children. The CDC has also found that food allergies impact nearly 8% of all children. Worse yet, a 2021 Northwestern study revealed that the adult onset of food allergies is a very real phenomenon as there are now more adults allergic to peanuts than children.

While food allergies are on the rise nationally, a 2020 study found that children on Medicaid were less than one-tenth as likely as children on private health insurance to be diagnosed with a food allergy. This is especially troubling in Oregon as the Kaiser Family Foundation found in 2023 that approximately 39.9% of the state's children are on Medicaid/CHIP.

Food allergies have a profound economic impact, and often harm those who can least afford it, as they cost the American economy more than $25 billion per year with the average family, in 2013, spending more than $4,000 in costs for each food allergic child. For those with a peanut allergy, which is generally a lifetime disease, a 2022 study found that the average cost is about $7,261 per individual per year from ages 1 to 18.

Worse yet, for a country with more than 33 million Americans with potentially life-threatening food allergies, up until February of this year, there was only one FDA-approved treatment for our community – Palforzia – and it was for children ages 4 to 17 with a peanut allergy.

Xolair's Promise and Oregon's Opportunity

On February 16th of this year, the FDA approved the use of Xolair to provide food allergy patients and their families with the protection we so desperately need. Xolair acts as a shield for food allergy sufferers and lessens the impact of accidental exposure to some of the top-nine allergens including

peanut, dairy, egg, and cashew. This is critically important given that once every ten seconds or roughly 3.4 million times a year, a food allergy reaction sends someone to the hospital or emergency room. In January of this year, we witnessed the all-too familiar tragedy of what happens when an individual comes into contact with their allergen as Orla Baxendale, a member of the Alvin Ailey Dance Company, passed away suddenly after accidental exposure to a mislabeled cookie product.

If the State of Oregon is going to unlock the full promise of Xolair and prevent future tragedies from happening, then we respectfully request that the Pharmacy and Therapeutics (P&T) Committee amend "Approval Criteria, #14" to read:

Food allergy: IgE-mediated food allergy with skin testing to confirm allergy OR double-blind placebo-controlled oral food challenge

Alternatively, we also support the elimination of the double-blind placebo-controlled oral food challenge.

A 2022 study summarized the problem with a double-blind oral food challenge which requires two test days, and are **"resource-intensive, time-consuming and expensive."** In addition, the American Academy of Allergy, Asthma and Immunology (AAAAI) found that "Blinded challenges are rarely performed in clinical practices, and are usually done in research studies." As a result, it would be nearly impossible for Oregon's food allergy population to take advantage of Xolair if the double-blind challenge is required.

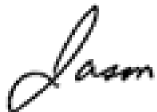
While the double-blind placebo controlled oral food challenge is notoriously difficult and expensive to administer and used primarily in research studies, there is a much simpler path forward – the traditional allergen skin test. FARE, along with the three most prominent physician organizations serving the food allergy community, the American Academy of Pediatrics, the American College of Allergy, Asthma, and Immunology, and the American Academy of Allergy, Asthma and Immunology (AAAAI) all endorse and use the allergen skin test as a safe, quick, and inexpensive way to diagnose food allergies.

We believe that if the true promise of Xolair is going to benefit the state's large food allergy community, then the diagnostic procedure to allow Xolair's use must be less restrictive than the double-blind oral food challenge. We encourage this Committee to either amend the diagnostic requirement to include the word "or" as noted above or better yet, completely remove the double-blind food challenge requirement.

If you have any questions about this comment, please contact me at Jlinde@foodallergy.org or at 301-693-7369.

Thank you.

Jason Linde



Senior Vice President, Advocacy
FARE
Contact: jlinde@foodallergy.org

July 31, 2024

To the Members of the Oregon Drug Use Review/ Pharmacy and Therapeutics Committee

It was brought to my attention by FARE (Food Allergy Research and Education NPO) that the criteria for using Xolair in patients with food allergy will be reviewed in your committee on August 1, 2024.

I have been a member of FARE for 21 years because I have two adult children whose lives are affected by food allergies.

My 19 year old daughter Brooke was diagnosed with a peanut allergy at 10 months of age. She began oral immunotherapy at age 5. Over the course of 11 years she developed a tolerance to peanuts and then began randomly reacting to her scheduled doses. Several hours after a scheduled dose she should tolerate she would develop airway constriction, increased heart rate, facial swelling and whole body hives. At age 16 she elected to discontinue oral immunotherapy and resume avoiding peanuts due to the emotional toll of unpredictable reactions to her doses. Brooke completed her freshman year at University of Montana this past May. In March 2024 for spring break, she took a backpacking trip to Capitol Reef National Park with five other students. The group meticulously planned their meals to ensure Brooke's safety on the trip. Despite this at 7pm on the fourth night of their trip in the Muhle Twists on the Burr Trail, Brooke experienced anaphylaxis in the backcountry. Anaphylaxis (or any emergency) in the backcountry means the trip ends for everyone. Brooke was hesitant to ruin the rest of the trip for her group but they urged her to use her epinephrine auto-injector. After the injection they started packing up their gear, after about 10 minutes her reaction was returning and she injected the second of four epinephrine auto-injectors she carries with her. She and another student began the six mile hike out of the park in the dark over terrain littered with boulders. The whole time she was calculating how severe her reaction was returning and if she could wait until the trailhead and vehicle to use a third epinephrine auto-injector. Fortunately for Brooke, the adrenaline of the whole situation took over. She successfully made it to the trailhead in an astounding few hours. Once there the other student drove her to the closest emergency room which was 2.5 hours away. Brooke called me at 2AM after she had been seen in the emergency room, given intravenous prednisone and discharged. The girls slept a few hours in the parking lot before heading back to the park and their group who waited for them at the trailhead. I spoke with park ranger Barbara Zirwas and the park director after the event and they concurred this was the fastest way to emergency services, activating SAR or even getting an ambulance to their trailhead would have taken longer.

At Brooke's allergist appointment in May 2024 upon her return home. Her allergist suggested investigating the cost and feasibility of Xolair as a way to

allow Brooke to enjoy backcountry adventures, hopefully avoiding more near misses with fatal anaphylaxis. Brooke hopes to be an au pair in Europe in the summer of 2025. She is planning a future career in pediatric occupational therapy or nurse midwifery. Those may sound like very different paths but both involve coaching an individual through difficulty and coaching is Brooke's speciality. She met an au pair from France when she was shadowing a pediatric OT practitioner this past May and jumped at the opportunity to combine a love of travel and a talent with young people.

Brooke is a young woman with hopes, dreams, and hobbies like every other young woman around the world. As a family we don't limit our children as a result of their food allergy, we support them in finding a way to manage their environment so they can pursue those hopes, dreams and hobbies with a modicum of safety. A therapeutic like Xolair, that could dampen Brooke's overactive immune response to peanuts, would do just that. There are hundreds, possibly thousands of food allergic individuals in Oregon who not only test positive to an allergen on a skin or blood test but have real life anaphylaxis stories just like Brooke. To discount these major life events and to require an individual who has experienced anaphylaxis, on potentially multiple occasions, upon exposure to their allergen to undergo a double blind placebo to prove they qualify is not only an unnecessary strain on medical practices and insurance providers but it is also an emotionally abusive requirement for these individuals.

Brooke completed oral food challenges multiple times in her short life as a part of oral immunotherapy and I can tell you with certainty if she had to do that again to qualify for Xolair she would refuse.

It is the compassionate and still medically appropriate choice to use allergist discretion in the prescription of Xolair for food allergic individuals. Please rethink the secondary criteria of a double blind oral food challenge. Many of the individuals and families considering this medication have already experienced significant trauma in learning about their food allergy.

Sincerely,

Amy Weinheimer
Hillsboro, Oregon