

Statement by Theodore Vallejos

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**To the Food and Drug Administration Pulmonary-Allergy Drugs
Advisory Committee**

**Re: BLA 103976, XOLAIR Omalizumab (Humanized Monoclonal
Antibody to Human IgE) for the treatment of allergic asthma**

May 15, 2003

**Holiday Inn
The Ballrooms
Two Montgomery Village Avenue
Gaithersburg, MD**

Hello, my name is Ted Vallejos. Thank you for taking the time to listen to me. I am here today with the help of the Asthma and Allergy Foundation of America, but my comments are on my own behalf. I hope that after listening to my history and experience with Xolair, this will help you make the decision to approve this new and amazing medicine. Throughout my adult life and the majority of my childhood, I have never experienced the freedom from asthma that I did for the short time I was on Xolair.

At the age of 7, I aspirated a silver tip of one of those old, black government/military pens and my life with asthma began. Since then, I have had ER visit after ER visit and hospital admission after hospital admission. My medical chart is the size of a large phone book. At the age of 13, my doctor told my parents that due to my asthma, we had to leave Hawaii. Of course, my brothers and sisters were not very happy.

I'm currently 38 years old, married, living in the sunshine, and working as a Respiratory Therapist in San Diego. The move to San Diego definitely decreased my ER visits and hospital admissions. From the ages of 7 to 24, I was admitted to the hospital about seven or eight times. In 1989—at the age of 25—I was intubated for the first time. I was again intubated in 1991. Another ICU admission followed a year later.

In 1994, a co-worker recommended I consult with Dr. Eli Meltzer who helped me gain control of my asthma. I have not been intubated, hospitalized, or gone to the ER since, but I always had to worry about wheezing and shortness of breath. Prior to seeing Dr. Meltzer in '94, I was wheezing daily and awakening almost every night from my asthma

attacks. I had to sleep with a nebulizer at my bedside. My upper airway was always mildly stuffy. My medications included Uniphyll 1200mg QD, Azmacort 4 puffs BID, Intal 4 puffs BID, using my albuterol inhaler 6-16 times a day (about a canister a month), and Prednisone bursts about 4-6 times a year. Dr Meltzer changed my regimen to albuterol nebulizers BID, Serevent BID, Uniphyll 1200mg QD, Aerobid 4 puffs BID (now on 4 puffs Flovent 220mc), albuterol MDI PRN, 20mg Prednisone QD (for about 4 months then changed to QOD), and Claritin (but now Allegra). This new regimen helped reduce my wheezing and cut my prednisone bursts to once or twice a year. For almost two years I tried allergy-desensitizing shots with no success. I could not get out of the first phase because my wheezing would flare up. I have also been taking Prilosec for my stomach pains and gastric reflux. I have tried Accolate (and now Singulair). Singulair has helped my symptoms a little and I have been weaned from my prednisone dose from 20mg QOD to about 10mg QOD.

Approximately two summers ago, I volunteered for the Xolair clinical research study. By the middle of the trial, I was feeling and breathing really well. My wheezing would rarely flare up and my nose was not as stuffy. In fact, by the end of the trial I was exercising on a regular basis. My breathing was so strong I started jogging. Until that time, I had never been able to run continuously for more than a mile in my 38 years.

Fortunately, I was able to receive Xolair for an additional three months after the trial. During that time, I was able to take myself off of Prednisone and the 1200mg of Uniphyll. I was also able to decrease my Flovent usage from 4 to 2-3 puffs each day. My PFTs

showed improvement—my FVC increased from the mid 80s to the mid 90s, my FEV₁ went from the mid 60s to the mid 70s, and my FEF₂₅₋₇₅ increased from the low to mid 30s to the mid 40s. My IgE blood level had dropped.

It was the best I had felt in a long, long time. I ran my first 5k run without stopping to walk. A month later, I ran another. It was amazing. I had my inhaler with me, but didn't need to use it. During the last two months on Xolair and even for a couple of months after, I was able to leave the house without my inhaler in my pocket. This was something I had never experienced before! Never in my life did I think I could leave home without it!

Unfortunately, it has been a little over a year since my last injection of Xolair. My asthma, wheezing, shortness of breath, stuffy nose, and having to have an inhaler in my pocket at all times has gradually returned. I actually still feel better than I did prior to the study. In fact, although I had never been able to participate directly in sports growing up, thanks to the benefits of Xolair I joined a softball team. My team is 7 and 1 and heading into the playoffs and I'm actually missing a game to be here with you today.

I'm currently in the middle of my second softball season and it is getting more difficult to run those bases. I tighten up very easily. I can no longer jog or run for pleasure. And, although I'm still off the prednisone, I'm back to 4 puffs of the Flovent, back on a little bit of Uniphyl (400mg), and Allegra (these along with the others I mentioned earlier—Singulair, Serevent, and Prilosec).

Another nice thing about Xolair was that it didn't give me the typical side effects like tremors, like the feeling of your heart pounding out of your chest, stomach pains, nausea, hunger, feeling tired, or my face looking like a moon (just to mention a few).

I believe that if I could continue with Xolair, I could maybe get by with only the maintenance drugs Flovent and Serevent. Perhaps someday I might get by with just Xolair.

I'm not sure. But I am sure that I could definitely live the rest of my life free of asthma.

I hope that my testimony here today helps you with your decision to approve Xolair for the difference it has made in my life and for so many others with allergic asthma.

I thank you very much for your time.