

**Statement by Jennifer Merenda, RN**

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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) by Genentech, Inc., for the treatment of allergic asthma**

**May 15, 2003**

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

Good afternoon. Thank you for your time today on this very important issue and thank you for allowing me to testify before your Committee. My name is Jennifer Merenda. I am a registered nurse with the R. Adams Cowley Shock Trauma hospital in Baltimore, MD, a wife, and a mother of two children. My comments today are on my own behalf and on behalf of my son, who also has asthma. The Asthma and Allergy Foundation of America has helped make my presence here today possible.

I have been waiting three very long years to tell you my story.

Since birth, I have had restricted airway problems. I spent the first two weeks of my life in the hospital because of breathing difficulties. I spent most of my early childhood years restricted in my activities, as medication to treat my chronic symptoms was not available. Instead, avoidance was supposed to be the best treatment, which was good in theory but was not practical in real life, especially for a child. I awakened many nights suffering with shortness of breath and made frequent retreats to my parents' room for assistance. I spent every Wednesday afternoon and every Saturday morning in my doctor's office for a minimum of one and a half hours while I received my allergy serum injection. I endured tenderness and swelling at the site that resembled an egg beneath the skin surface. Winter nights were spent in my bedroom with a vaporizer and frequent chest physiotherapy. I would be sent home from school because I "looked" like I was having too much trouble breathing, even as I pleaded to stay.

I stopped allergy injections in my early teens as there did not seem to be any real benefit. I began to use Primatine Mist as that was the most useful over-the-counter medication at the time. I grew tired of the doctor's office. As I grew into my late teens my breathing and allergies worsened. I was tired of medicine. I was tired of reading every food label. I was always taught to deal with my health problems and not use asthma as an excuse. I didn't want sympathy from anyone. I would rather enjoy life, wheeze, take my inhaler and move on. I guess that was part of being a teen.

At the age of 17, I finally realized that my asthma was not controlled. I began my allergy injections again and was prescribed Theopholine twice a day with Ventolin for breakthrough wheezing. While both drugs certainly helped my asthma, I experienced several side effects. Eventually I changed to a sustained release form of the Theopholine and had more control, but again, not without the side effects. Along came Serevent, and though I continued to have my problems, I felt it was under control. Little did I know what control could be, however, until a friend of mine with asthma told me about a new clinical trial.

When I joined the Xolair trial in August of 1998, I was told the FDA did not yet approve the drug being tested, but that if I got the drug instead of placebo I would most certainly see improvement. Truth is, I didn't feel like I had anything to lose and my expectations were quite low. To qualify for the trial, I had to stop current medications. This was the most difficult part, as I had to restrict my activities because of shortness of breath. I couldn't even walk a flight of stairs.

I can't emphasize enough for you my surprise with this miracle injection I began to receive. I did not experience any local effects at the injection site and my asthma symptoms were completely alleviated. While I received the Xolair injections, I experienced the life of a normal person. I say this because prior to Xolair, people in my life would say "you're breathing heavy again" or "I can hear you coming around the corner before I see you."

With Xolair, I stopped clearing my throat and coughing frequently. I could go anywhere without the fear of losing my inhaler. I was no longer concerned about needing to have an inhaler in every coat, in every pair of pants, in my car, or in a relative's home. I was not afraid to go on vacation and be without a nebulizer machine. I did not make noise breathing. I slept quietly. I did not walk around with my mouth open. I did not have to worry about restrictive clothing. My nose worked and was no longer what I refer to as "purely cosmetic...serving no function." I was truly free. For the first time in my life, I felt like everyone else did not have his or her "eyes of concern" focused on me.

I told you in the beginning that I've waited three long years to tell you my story. That's because when the Xolair clinical trial ended three years ago, I immediately returned to a life of daily asthmatic symptoms. I felt I had something great and now it's gone. I am a registered nurse. I work in a center that is known worldwide. I continue to praise this miracle drug to physicians and colleagues that I work with daily. I field questions from other patients about the drug that once relieved me from the misery of my asthma.

And as a nurse, I'll be the first to say that prevention is where health care starts. Prevention is what Xolair is all about as far as I'm concerned. The fact is, it is difficult for patients to understand why a drug that has demonstrated so much promise has not been approved yet. I continue to be asked by my colleagues, and by my family and friends, about where the drug is currently in the approval process. I not only think of myself though. I think about how many emergency room visits for people with asthma

could be eliminated. I think of my son and the potential for his life to be free from continuous medication and constant fear. I look to the future and hope that many more people with asthma will know what it means to lead a normal life. I sincerely believe Xolair can provide that freedom. I urge you today to recommend that this drug be approved.

Again, thank you for your time and for allowing me to share my story.