

**FDA
BLOOD PRODUCTS ADVISORY COMMITTEE
MEETING**

**STATEMENT OF JUDY RANALLO
PRESIDENT, OHIO CHAPTER**

**ON BEHALF OF:
IMMUNE DEFICIENCY FOUNDATION**

MARCH 26, 1999

Good morning, my name is Judy Ranallo and I am President of the Ohio Chapter of the Immune Deficiency Foundation. As you are aware the chronic shortage of IGIV has been ongoing since the fall of 1997, a situation that as the mother of an immune deficient patient has gone on far to long. For my son Sam, IGIV is the difference between life and death; this is also the case for many thousands of patients and their families for whom IGIV is life sustaining. I am here today to address this Advisory Committee because the current shortage should not be allowed to continue. Solutions must be found. Therefore, the licensure of new IGIV preparations is of great personal concern to me.

My son Sam was born in February of 1983. Sam was premature, diagnosed as developmentally delayed, and was placed on a series of medications to treat low blood sugar and a seizure disorder. He did not respond well to the medications prescribed and at the age of four began having a series of serious infections. In a two year period Sam had three surgeries, tubes were placed in his ears, his tonsils were removed and he had upper GI problems. As a result he suffered hearing loss and was not allowed to return to school due to his severe health complications. He was then diagnosed with asthma and epilepsy. He had skin infections, which would not heal, and his sinus passages were destroyed due to infection. Sam averaged twelve to fifteen serious infections per year, many of which required hospitalizations. His health was not improving and he continued to deteriorate, making our life a nightmare. Finally at the age of seven Sam was properly diagnosed as immune deficient and placed on IGIV infusions. Sam has continued to receive IGIV every three weeks for the past nine years. In fact last summer we had a party for his 100th infusion, which we celebrated with family and friends. Since beginning IGIV therapy he has not had serious infections and the rate of infection has dropped from twelve to fifteen serious infections per year - to two or three minor infections. Sam is here today and will tell you a little bit about himself and his wonderful accomplishments.

For me as a mother, I know that my son is at risk of developing an infection that could seriously debilitate or kill him if he doesn't receive IGIV every three weeks. It is this fear that brings me here today on behalf of my family and the thousands of people whose lives depend on regular IGIV infusions. We often do not know if our infusion will take place as scheduled until 24 hours in advance. Imagine living with the knowledge that IGIV means a healthy "normal" life for my son and knowing that it may not be available to him tomorrow.

Solving the current IGIV shortage and increasing the supply in the US marketplace is the responsibility of manufactures, government and patient organizations. In Congressional hearings held in May of 1998 the FDA stated that new products entering the marketplace could increase supply. To date, no new IGIV preparations have been licensed, and only one significant licensing trial is underway. I hold you responsible for finding ways to expedite licensure, and increase supply to ensure that the thousands of patients for whom this product is life sustaining are able to receive their treatment. For my son and many others this is a situation where failure is not an option.

Thank you. I would be happy to answer any questions you may have.