

## **CALL TO ACTION BY THE ALS COMMUNITY RESULTS IN SETTLEMENT AGREEMENT TO RELEASE IPLEX!**

A Successful Public Protest, Advocacy and Demonstration took place in Washington DC on Tuesday, November 11, 2008. Team Iplex, an organization of ALS patients and caregivers who devote their time, energy and resources toward securing IPLEX for those with ALS convinced Genentech, Tercica and Insmed to resolve their legal dispute and release IPLEX to the ALS community. A deluge of letters, emails and phone calls resulted in an agreement reached on November 7, 2008, just days before the demonstration took place.

Nearly 100 participants gathered in front of the U.S. Capitol Building to draw attention to the plight of ALS patients. Literature was passed to inform the public and buttons distributed. Patients, caregivers, friends, relatives, reporters, filmmakers came to give their support to the cause.

But the fight is not over. As of January 8, 2009, IPLEX remains unavailable to the ALS community. ALS WORLDWIDE has helped dozens of patients through the IND/IRB protocol required by the FDA. But we have just learned that the FDA has rejected Iplex usage by ALS patients due to 'unsubstantiated claims of higher mortality' and 'excessive blogger interest in Iplex.' The fight continues.

### **The Story Behind IPLEX**

Genentech, a developer of biotechnology products, invented Increlex, a synthetic IGF-1 growth hormone to combat severe short growth stature, also known as dwarfism, in infants and young children. Genentech then licensed Tercica for its manufacture and distribution.

IPLEX, manufactured by Insmed, is an improved version of Increlex but it infringed upon the patents owned by Genentech and Tercica. In a closed settlement agreement announced on February 17, 2007, Insmed was prevented from distributing IPLEX to the 'short stature' population. At that time, the worldwide ALS community also lost access to IPLEX (except for Italy, due to a settlement exclusion based upon a prior agreement between Insmed and the Italian Ministry of Health).

As of November 7, 2008, Genentech and Tercica relinquished all rights to any royalties for IPLEX provided to the ALS community.

### **What Can You Do to Support the ALS Community?**

- 1. Call and/or write Congress urging them to write a 'Morality Law' that supersedes patents, costs and FDA sanctions in cases of incurable diseases such as ALS.  
Senate & Representative Switchboard: 202-224-3121**
- 2. Be Informed! ALS strikes, without warning -- anyone, anywhere, anytime.  
More cases than ever before are being diagnosed every day. ALS is as**

commonly diagnosed as Multiple Sclerosis. The difference is that ALS patients die within two to four years.

3. Educate your friends and family about ALS. Citizens must demand Justice for Patients' Rights.
4. Be Aware! The travesty of an unavailable medication can happen to any patient suffering from any disease. Breast Cancer – AIDS - Leukemia
5. Become aware of ALS and how it devastates patients and entire families.
  - a. Read about Ben Byer's journey with ALS at [www.indestructiblefilm.com](http://www.indestructiblefilm.com)
  - b. Purchase a DVD of his award winning documentary film "INDESTRUCTIBLE" and share it with your community.