

February 13, 2007

The Honorable Henry Waxman
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Waxman:

The National Organization for Rare Disorders (NORD) and the 25 million men, women, and children we represent deeply appreciate your efforts to provide the FDA a legal pathway to create a well-defined regulatory abbreviated pathway for comparable biologic products based on rigorous, scientific standards. For this reason, we are writing in support for the bipartisan introduction of the “*Access to Life- Saving Medicines Act of 2007.*”

Millions of Americans affected by one of the 6,000 known rare diseases rely on the lifesaving properties of biologics to sustain or improve the quality of their lives – twenty-one percent of the 304 orphan drugs on the market today are biologics. For many chronic rare disorders, the cost of treatment for just one year is equivalent to buying a new house every year for the rest of their lives. We need safe, effective and affordable comparable biologic alternatives to help respond to this challenge. And, as you know, we are not late to the game on this issue. In fact, in March 2003, we sponsored the first national symposium to explore the feasibility of follow-on biologics. Experts from around the world were invited to raise the questions and seek the answers to whether Americans, including the millions with rare diseases, should have the chance to purchase safe and less expensive comparable biologics.

While we have not had time to review all the details of the bill and, as such, cannot yet extend a formal endorsement at this time, we know you share our commitment for the establishment of a long-overdue, abbreviated and science-based safe pathway for comparable biologics. We are confident that your legislation is designed to achieve this outcome. To that end, we are also pleased that you provide necessary and desirable discretion for FDA scientists to make judgments about comparability and interchangeability of biotech products.

Again, NORD strongly commends you for your work and your legislation to provide safe, quality and less expensive biologic alternatives for rare disease patients. We look forward to working with you and your colleagues to get legislation enacted this year. With your leadership, we are confident that the promise of comparable and interchangeable biologics can finally be achieved.

Sincerely,

Abbey S. Meyers
President

Cc: Carolyn Asbury, Chairman of the Board
Diane Edquist Dorman, Vice President, Public Policy