



American Autoimmune

Related Diseases Association, Inc.

www.aarda.org

A nonprofit association bringing a national focus to autoimmunity, the major cause of chronic disease

July 16, 2009

The Honorable Anna G. Eshoo
House of Representatives
205 Cannon Building
Washington, D.C. 20515

Dear Ms. Eshoo:

The American Autoimmune Related Diseases Association (AARDA) would like to convey our support of your forthcoming compromise amendment to H.R. 1548. We support this amendment because of the steps it takes in protecting biologic innovation in providing for a 12-year period of exclusivity provision.

AARDA is an ardent supporter of the development of biosimilars. However, our support is dependent on seeing biosimilars coming to market in a way that ensures patient safety without thwarting innovation. While in attendance at your hearing yesterday, July 15, I was impressed with your commitment to patient safety; this is a primary reason for which AARDA supports this forthcoming amendment. In addition to patient safety, it is imperative to those we represent to protect the future pipeline of innovation through allowing biotech firms the data exclusivity period necessary to ensure continued advancement in the area of biologic development. We believe that the 12-year period proposed in your proposed amendment meets this criterion.

In representation of the 23.5 million Americans who suffer from some form of autoimmune disease, AARDA looks with hope on the future of biologic innovation. Prior to the development of biologics, autoimmune disease patients had not seen any new treatments which substantially increased their quality of life in nearly 50 years.

AARDA is a national nonprofit voluntary health organization representing the millions of Americans who have one or more of the 100+ autoimmune diseases (and 75 percent of those are women). It is the only national organization dedicated to addressing the problem of autoimmunity, the major cause of chronic illness. Some of the over 100 autoimmune diseases are lupus, type I diabetes, scleroderma, celiac, multiple sclerosis, Crohn's disease, autoimmune hepatitis, rheumatoid arthritis, Graves' disease, and myasthenia gravis.

Thank you for your continuing efforts to bring biosimilars to market in a safe and effective manner for patients who depend on biologics to enhance their quality of life from debilitating chronic disease. If we can provide any assistance, we stand ready to help.

Sincerely,

Virginia Ladd
Executive Director/President