



# American Autoimmune

Related Diseases Association, Inc.

[www.aarda.org](http://www.aarda.org)

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

March 18, 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) is pleased to endorse your bill, "Pathways for Biosimilars Act." We are particularly pleased with the data exclusivity language.

In general, we approve of biosimilars for the benefit of patients with autoimmune diseases and the language provided in the bill, with the exception of one concern that we believe could jeopardize patient safety.

We would like to register concern regarding the language that provides for the Secretary's ability to waive the requirement for conducting studies to assess the immunogenicity of biosimilars. Our concern for the decision's being made on the current state of scientific knowledge is based on the fact that biologics have not been around long enough to determine the potential long-term effects of their immunogenicity.

AARDA is a national nonprofit voluntary health organization representing the approximately 23 million 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.

We thank you for your attention to the deep concerns of your constituents as well as many, many others in this biosimilars area of health care. If we can provide any assistance, we stand ready to help.

Sincerely,

Virginia T. Ladd  
President and Executive Director