



# ASSOCIATION OF AMERICAN UNIVERSITIES

- Brandeis University
- Brown University
- California Institute of Technology
- Carnegie Mellon University
- Case Western Reserve University
- Columbia University
- Cornell University
- Duke University
- Emory University
- Harvard University
- Indiana University
- Iowa State University
- The Johns Hopkins University
- Massachusetts Institute of Technology
- McGill University
- Michigan State University
- New York University
- Northwestern University
- The Ohio State University
- The Pennsylvania State University
- Princeton University
- Purdue University
- Rice University
- Rutgers, The State University of New Jersey
- Stanford University
- Stony Brook University – State University of New York
- Syracuse University
- Texas A&M University
- Tulane University
- University at Buffalo – State University of New York
- The University of Arizona
- University of California, Berkeley
- University of California, Davis
- University of California, Irvine
- University of California, Los Angeles
- University of California, San Diego
- University of California, Santa Barbara
- University of Chicago
- University of Colorado, Boulder
- University of Florida
- University of Illinois, Urbana-Champaign
- University of Iowa
- University of Kansas
- University of Maryland, College Park
- University of Michigan
- University of Minnesota, Twin Cities
- University of Missouri, Columbia
- University of Nebraska - Lincoln
- University of North Carolina at Chapel Hill
- University of Oregon
- University of Pennsylvania
- University of Pittsburgh
- University of Rochester
- University of Southern California
- University of Texas at Austin
- University of Toronto
- University of Virginia
- University of Washington
- University of Wisconsin - Madison
- Vanderbilt University
- Washington University in St. Louis
- Yale University

June 10, 2008

The Honorable Anna Eshoo  
205 Cannon House Office Building  
Washington, DC 20515

The Honorable Joe Barton  
2109 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives Eshoo and Barton:

I write on behalf of the Association of American Universities (AAU), which represents 60 leading U.S. research universities, to convey our strong support for H.R. 5629, the “Pathway for Biosimilars Act.” This bill effectively implements a balanced policy that we strongly endorse: providing access to safe, effective and affordable biologic treatments while continuing to promote the innovative research and development in the life sciences that will fulfill the promise of current and future discoveries and treatments.

The critical aspects of biosimilars legislation for universities are those provisions that affect their ability to transfer biotechnology research into the commercial sector for development into medicines and treatments that advance public health, including providing new treatments for some of the most intractable diseases.

Universities conduct basic research that yields early-stage discoveries. To ensure that these discoveries will benefit the public, innovator companies and venture capitalists must have sufficient economic incentives to commit the substantial investments necessary to conduct clinical trials and develop such discoveries into new, breakthrough biologic treatments. Your bill accomplishes this objective by providing innovators 12 years of data exclusivity; the bill also usefully provides an additional two years of exclusivity for approval of medically significant new indications, and an additional six months of exclusivity for completing pediatric studies.

It is also important for universities, which hold many of the patents on fundamental biotechnology inventions, to be able to participate in an effective and efficient process for resolution of any patent disputes raised by the biosimilar applicant. H.R. 5629 preserves the ability of third-party patent holders such as universities to defend their patents in such disputes. However, we do hope that as the bill moves forward, a provision can be included through which third-party patent holders, in addition to reference product manufacturers, are notified directly of FDA acceptance of a biosimilar application.

H.R. 5629 provides an effective, balanced process for preserving patient safety, promoting innovation, and encouraging competition. We commend you for your introduction of this important legislation and look forward to working with you to secure its passage into law.

With best regards,

Robert M. Berdahl  
President