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June 3, 2009

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

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

The Honorable Jay Inslee
403 Cannon House Office Building
Washington, D.C. 20515-4701

Dear Representatives Eshoo, Inslee, and Barton:

I write on behalf of the Association of American Universities, which represents 60 leading U.S. research universities, to convey our strong support for H.R. 1548, the “Pathway for Biosimilars Act.” This bill effectively balances national priorities in providing access to safe, effective and affordable biologic treatments while continuing to promote the innovative research and development in the life sciences that will deliver future discoveries and treatments.

The critical aspects of biosimilars legislation for universities are those provisions that ensure their ability to transfer biotechnology research into the commercial sector for development into medicines and treatments that advance public health.

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 develop such discoveries into new, breakthrough biologic treatments. H.R. 1548 accomplishes this objective by providing 12 years of data exclusivity to innovator companies. 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.

Because universities hold many of the patents on fundamental biotechnology inventions, it will be important that they be able to participate in an effective and efficient process for resolution of any patent disputes raised by a biosimilar applicant. H.R. 1548 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. 1548 provides an effective, balanced process for preserving patient safety, promoting innovation, and encouraging competition. We commend you for introducing this important legislation and look forward to working with you to secure its passage into law.

With best regards,

Robert M. Berdahl
President