

July 14, 2009

Robert M. Berdahl  
President  
American Association of Universities  
1200 New York Avenue, NW, Suite 550  
Washington, DC 20005

RE: June 3, 2009 AAU Endorsement of Eshoo-Inslee-Barton Follow-on Biologics Bill

Dear Dr. Berdahl,

We, the American Medical Student Association, Essential Action, and Universities Allied for Essential Medicines, representing consumers and tens of thousands of students at top research universities in the U.S. and abroad, write to demand that you immediately withdraw AAU's support for the 12 years of brand exclusivity included in H.R. 1548, the "Pathway for Biosimilars Act." The brand exclusivity term of 12 years in the legislation<sup>1</sup> is unjustifiably long, will cost consumers billions of dollars, and reach beyond our borders to restrict access to lifesaving treatments in developing countries. Your claim that 12 years of exclusivity is necessary for continued innovation is contradicted by economic analysis, including one recent report from the Federal Trade Commission<sup>2</sup>.

As you well know, healthcare costs are out of control, leading to over 60% of bankruptcies in the United States<sup>3</sup>, and government contributions to medicines for developing countries are dropping. Congress is now considering ways to control healthcare costs. It is unconscionable that universities, which are non-profit organizations ostensibly dedicated to the dissemination of knowledge for the public good, support a measure that will dramatically restrict access to affordable medicines and likely cost consumers and the federal government billions of dollars. We strongly believe that developing a process for getting biosimilars to market is a critical step in furthering access to affordable medicines. However, the counter-productive provisions of H.R. 1548 are not necessary to develop such a process. The "Promoting Innovation and Access to Life-Saving Medicine Act" introduced in both the House (H.R. 1427) and the Senate (S.726), and specifically its 5-year term of exclusivity, will open the same doors, without imposing such high costs on consumers.

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<sup>1</sup> <http://www.aau.edu/WorkArea/DownloadAsset.aspx?id=9016>

<sup>2</sup> See Federal Trade Commission, *Emerging Health Care Issues: Follow-On Biologic Drug Competition*, June 2009. Available at: <http://www.ftc.gov/opa/2009/06/biologics.shtm> and Henry Grabowski, *Outlook: Follow-on biologics: data exclusivity and the balance between innovation and competition*. *Nature Reviews Drug Discovery* 7, 479-488 (June 2008). Available at: <http://www.nature.com/nrd/journal/v7/n6/full/nrd2532.html>.

<sup>3</sup> Arnst, Catherine. "Study Links Medical Cost and Personal Bankruptcy." *BusinessWeek* June 4, 2009. Available at: [http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064\\_666715.htm](http://www.businessweek.com/bwdaily/dnflash/content/jun2009/db2009064_666715.htm).

Universities must take evidence-based stances that benefit society, and not simply act as echo chambers for PhRMA and BIO priorities. Given the lack of evidence and the option to do better, the AAU must rescind its support of H.R. 1548 and its 12 year term of exclusivity.

Signed:

American Medical Student Association  
Essential Action  
Universities Allied for Essential Medicines

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cc:

AAU Member University Presidents  
Senator Edward Kennedy  
Senator Charles Schumer  
Senator Michael Enzi  
Senator Charles Grassley  
Congressman Frank Pallone  
Congressman Nathan Deal  
Congressman Henry Waxman