



April 16, 2009

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

RE: AAU Endorsement of Eshoo-Barton Follow-on Biologics Bill

Dear Dr. Berdahl,

We write to you to express our deep disappointment that despite positive bi-partisan follow-on biologics legislation, the Promoting Innovation and Access to Life-Saving Medicine Act introduced in both the House (H.R. 1427) and the Senate (S.726), the AAU has once again supported the Eshoo-Barton bill (H.R.1548) which contains unreasonable terms of data exclusivity.

As we stated in our previous letter, the AAU letters dated May 2, 2008<sup>i</sup> and June 10, 2008<sup>ii</sup> in support of this legislation make clear that these exclusivity terms are intended to increase patent rents on biologics and will achieve two primary goals: delaying the onset of generic competition beyond the expiration of the patent term and inhibiting patent challenges. In addition to our concern that these objectives will be achieved at the expense of access to medicines, we question why the AAU would take a position on an issue that has exclusively commercial consequences, unrelated to the non-profit mission of the university.

Furthermore, when universities do take positions, they must be based on the best available evidence, which this is not. In reaffirming support for the Eshoo-Barton bill, the AAU once again offers as justification the questionable assertions of the biotechnology and pharmaceutical industry regarding cost recovery. You made the same claim regarding cost recovery in your November 12, 2008 letter to us but have repeatedly failed to provide data supporting this assertion.

In fact, this cost-recovery claim is at odds with a study<sup>iii</sup> funded by the Pharmaceutical Research and Manufacturers of America (PhRMA), which concluded that break-even lifetimes for small molecule drugs and biologics are almost identical (12.5 to 16 years versus 12.9 to 16.2 years). The same study noted that the mean development time for biologics is only 7.4 months longer than that for small molecules. Though we might question the objectivity of the study on certain points given its provenance, the conclusion, which one would expect to skew in favor of industry, undeniably contradicts the argument now being advanced by the AAU in conjunction with PhRMA and the Biotechnology Industry Organization.

Moreover, the cost of reverse-engineering and regulatory approval will be higher for follow-on biologics than for small-molecule generics. These harsher natural barriers to market entry by competitors suggest that brand-name biologics will be subject to relatively light

competition even in the absence of data exclusivity protection. A recent study estimated that each follow-on biologic entry in the US would involve a time delay of 5-8 years<sup>iv</sup>, whereas the process of reverse engineering a small molecule drug can take as little as 6 months.

Given these facts, a data exclusivity period of 12 to 14.5 years – in contrast to the 5-year data exclusivity period for small molecules – is unacceptably excessive and morally indefensible.

Alternative follow-on biologics legislation is now available. The AAU has a choice and is choosing to place itself on the wrong side of the debate between fostering innovation with access and pursuing commercial profit at the expense of human lives. We once again request that the AAU, as the representative of major research universities who are ostensibly pursuing the creation and dissemination of knowledge for the public good, withdraw its support of H.R.1548.

Sincerely,

A handwritten signature in black ink, appearing to read 'E. Guillen', is written over a light gray rectangular background.

Ethan Guillen  
Executive Director  
Universities Allied for Essential Medicines

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

---

<sup>i</sup> [http://www.aau.edu/intellect/Ltr\\_Berdahl\\_Pallone-Deal\\_FOB\\_5208.pdf](http://www.aau.edu/intellect/Ltr_Berdahl_Pallone-Deal_FOB_5208.pdf)

<sup>ii</sup> [http://www.aau.edu/intellect/Ltr\\_Berdahl\\_Eshoo-Barton\\_Followon-Biologics\\_6-10-08.pdf](http://www.aau.edu/intellect/Ltr_Berdahl_Eshoo-Barton_Followon-Biologics_6-10-08.pdf)

<sup>iii</sup> 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>iv</sup> Henry G. Grabowski, David B. Ridley and Kevin A Schulman, *Entry and Competition in Generic Biologics*, 28 Manage. & Decis. Econ. 439, 442-3 (2007)