

## UNIVERSITIES ALLIED FOR ESSENTIAL MEDICINES

<http://www.essentialmedicine.org/>



October 15, 2008

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,

I write to express the concern of Universities Allied for Essential Medicines (UAEM) regarding your recent endorsement of the Eshoo-Barton Follow-on Biologics Bill on behalf of our universities. UAEM is a coalition of student groups across the US, Europe and Canada that works to expand access to the fruits of university research. Our member chapters include many campuses represented by the American Association of Universities (AAU).

The need for a regulatory pathway for approving follow-on biologics is self-evident and pressing. However, the Eshoo-Barton legislation contains several objectionable elements, foremost being the contemplated 12-year term of exclusivity for market registration data with additional extensions available for new indications and pediatric testing.

As your letters<sup>1,2</sup> dated May 2 and June 10, 2008 make clear, 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 clearly has commercial consequences, unrelated to the non-profit mission of the university.

In addition to a delayed onset of generic competition, an increased term of data exclusivity will have a profound impact on efforts to combat epidemic diseases in the developing world. Some developing country governments and large global health buyers, including the President's Emergency Plan for AIDS Relief (PEPFAR) and USAID, require that drugs achieve US FDA approval before they can be designated for purchase. The FDA has instituted a narrow exception allowing "tentative approval" of generic fixed-dose combination anti-retrovirals (FDC ARVs) despite data exclusivity – there is no suggestion this narrow pathway will be extended to encompass approval of generic biologics for use in developing countries. An extended term of data exclusivity in the US will curtail the ability of some global health buyers to source generic versions of important new drugs, even for countries in which there is no patent protection or for which humanitarian licenses are available. Given the very high cost of brand biologics, these drugs could remain beyond the reach of many of the world's poorer populations.

Last year, the nation's foremost research universities issued the Stanford Nine Points, a joint statement that "universities share certain core values that can and should be maintained to the fullest extent possible in all technology transfer agreements."<sup>3</sup> Mindful of constraints on access and future innovation, the Nine Points state that "[u]niversities need to be mindful of the impact of granting overly broad exclusive rights and should strive to grant just those rights necessary to encourage

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development of the technology.” While specific to licensing, the Nine Points capture the concern of universities’ technology transfer and scientific communities that granting of market exclusivities should not impede universities in fulfilling their missions and realizing their core values.

Advocating for a lengthy term of data exclusivity is at odds with universities’ mission to create and disseminate knowledge in the public interest. Not only would extended exclusivity restrict access to medicines: fundamentally, data exclusivity creates legal barriers that prevent regulators from relying on the best available scientific data in decision making. Artificial barriers to knowledge are not consistent with the core values universities stand for.

Further, while UAEM is concerned primarily with impacts on global access, we do note that effectively extending patent terms will increase university patent rents marginally at a cost in the billions of dollars to US consumers. Likewise, insulating bad patents will impose large additional costs on US consumers with limited benefit to universities.

Universities must work in partnership with industry to advance basic research into the marketplace, but the academy must be careful to maintain an independent voice that is true to its core mission. The AAU’s co-endorsement of this BIO-backed legislation calls this independence into question.

University co-endorsement of pharmaceutical industry priorities has developed as a disturbing trend. In April of this year, UAEM called on the Association of University Technology Managers (AUTM) to retract a letter urging its members to sign the Institute for Policy Innovation’s Open Letter to the World Health Organization (WHO) opposing – along with PhRMA and BIO – exploration of non-patent means of increasing research on neglected diseases and access to medicines. Subsequently, AUTM clarified its position and distanced itself from the IPI letter, and efforts continue to move toward the creation of high-dollar prize funds to stimulate research on TB, Chagas and other neglected diseases.

In the wake of the AUTM clarification, a group of prominent academics, Nobel laureates and technology managers issued a call to universities “to begin a new, open process for setting policies regarding the funding and licensing of basic science.”<sup>4</sup> “The event [at WHO],” the letter observed, “is a symptom of a larger problem at universities: Our positions on questions of research, global development, and technology transfer have never been set in an open, community wide debate. . . This situation must change. Basic questions of scientific research, university technology transfer, and their relation to access to knowledge and development should properly be addressed by the governing bodies and faculties of the universities. . . AUTM should not be speaking in the name of the university community as a whole.”

UAEM looks forward to the establishment of this open, community wide debate, and we hope that the AAU and your member universities will work with us to create a forum and a process through which consensus university positions can be reached.

UAEM urges that you withdraw your endorsement and retract your letter and comment on the Eshoo-Barton Follow-on Biologics Bill. We also urge that if and when follow-on biologics legislation is introduced in the next Congress, the AAU refrain from commenting on the bill in a manner inconsistent with the non-profit mission of the university.

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UAEM does not object to the AAU testifying to the importance of a regulatory pathway for biologics in a manner in line with the fulfillment of the non-profit mission of the university. However, UAEM would urge that the AAU expressly decline to take positions on issues such as data and marketing exclusivity, and other issues primarily concerned with commercial interests that call into question the underlying motivations of universities.

We look forward to your response to this letter and to establishing a broader dialog on this topic.

Sincerely,

Ethan Guillen  
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cc:

AAU Member University Presidents  
Senator Edward Kennedy, Chair, Health, Education, Labor and Pensions Committee  
Senator Mike Enzi, Ranking Member, Health, Education, Labor and Pensions Committee  
Senator Charles Grassley, Ranking Member, Committee on Finance  
Congressman Frank Pallone, Chair of Subcommittee on Health  
Congressman Nathan Deal, Ranking Member, Subcommittee on Health

### AAU Member Universities with a UAEM Chapter

Columbia University	University of California-San Diego
Cornell University	University of Florida
Duke University	University of Indiana
Emory University	University of Michigan-Ann Arbor
Harvard University	University of North Carolina - Chapel Hill
Johns Hopkins University	University of Pennsylvania
McGill University	University of Southern California
Stanford University	University of Toronto
University of California-Berkeley	University of Washington
University of California-Irvine	University of Wisconsin
Vanderbilt University	Yale University
University of California-Los Angeles	

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

2 [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)

3 <http://news-service.stanford.edu/news/2007/march7/gifs/whitepaper.pdf>

4 <http://www.essentialmedicine.org/eminent-academics-igwg-delegates-should-explore-new-mechanisms-to-correct-current-deficiencies-in-medicine-system/>