



## ASSOCIATION OF AMERICAN UNIVERSITIES

*President*

November 12, 2008

Ethan Guillen  
Executive Director  
Universities Allied for Essential Medicines  
2625 Alcatraz Avenue #180  
Berkeley, California 94705

Dear Mr. Guillen:

Thank you for your letter expressing the concerns of Universities Allied for Essential Medicines (UAEM) about the endorsement by the Association of American Universities (AAU) of H.R. 5629, the “Pathway for Biosimilars Act” as introduced by Congresswomen Eshoo (D-CA) and Congressman Barton (R-TX). Your letter states that you are particularly concerned about our support of that legislation’s provision of 12 years of data exclusivity, questioning “why the AAU would take a position on an issue that clearly has commercial consequences, unrelated to the non-profit mission of the university.”

The answer to this question is stated in the second paragraph of our June 10 letter endorsing H.R.5629:

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.

The commercial development of university early-stage discoveries into effective medicines and treatments is a high-cost, high-risk endeavor. Universities discover and transmit technology in a real-world market environment. The reality of the market-driven drug development system is that without adequate provision for the recovery of costs by commercial firms carrying out the development of university discoveries, such development will not occur. In the case of biologics, the development process is especially complicated and costly.

Your letter suggests that federal regulations should prescribe no or a minimal period of data exclusivity in order to allow generic companies to develop low-cost follow-on biologics as soon as new biologics are created. It is surely desirable to create lower-cost generic alternatives to biologics, but without a sufficient period of data exclusivity supporting reasonable cost recovery

by the commercial firms that create these new biologics, those firms will not acquire university discoveries and invest in the substantial additional R&D necessary to produce path-breaking biologics. The result in such cases will not be low-cost follow-on biologics but no biologics.

AAU shares the stated goal of UAEM to promote the availability of low-cost medicines and therapies in developing countries. That goal must be pursued within the economic realities of the research and development system. Both within and outside that system, there are numerous opportunities for universities to play an effective role in expanding access to low-cost medicines in developing countries, and we are working with our member universities and other actors in this system to promote such opportunities. Universities seek to advance human welfare in multiple ways, including by teaching students, by publishing faculty discoveries in the scholarly literature, and by engaging in direct service to local and global communities, including helping the private sector bring medicines, devices, and other useful products to the market. You are correct that developing faculty discoveries and translating them into commercially viable products is outside of the mission and expertise of universities. That is why universities work with government agencies and non-profit as well as for-profit organizations and companies in the development of faculty discoveries for the benefit of the global community.

While we share your goal of providing low-cost medicines in developing countries, we disagree with your analysis of the means of achieving that goal and with the application of that analysis to the Eshoo-Barton bill. I will also note that we disagree with your characterization of our endorsement of the bill as a “co-endorsement of this BIO-backed legislation.” We reached our decision after consultation with a number of parties involved in the production of medicines and treatments that benefit mankind, and with colleagues within our sector and elsewhere who have a particular focus on bringing critical medicines to developing countries. This input and our analysis of how university research can advance the public good most effectively in bringing new discoveries to the market led to our endorsement of the Eshoo/Barton bill. Contrary to your assertion that our support of the Eshoo/Barton data exclusivity provision was driven by an intent to increase “university patent rents,” our support is driven by our interest in moving university discoveries into the commercial sector for development into therapeutic products that benefit of the public, and our recognition that reasonable cost recovery by the commercial firms carrying out that development is a necessary component of the overall process.

AAU will continue to look for opportunities to collaborate with all organizations that share the goals of supporting the research and development needed to create new medicines and treatments, and of creating ways to deliver these much-needed therapies to developing countries in timely, effective, and affordable ways.

Sincerely,



Robert M. Berdahl  
President