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For Immediate Release

**AAU ONCE AGAIN ENDORSES LEGISLATION THAT WILL IMPEDE
ACCESS TO AFFORDABLE BIOLOGIC DRUGS**

UAEM CALLS ON AAU TO WITHDRAW SUPPORT

The Association of American Universities (AAU) has once again endorsed legislation, (newly numbered H.R. 1548 in the new Congress), that would impede access to lower-cost follow-on biologics such as vaccines and cancer treatments. The AAU previously declined to withdraw its endorsement from H.R. 5629 of the previous Congress, the “Pathway for Biosimilars Acts,” following a call to do so from Universities Allied for Essential Medicines (UAEM). The new bill, as with the previous one, would effectively increase the length of patents on biologic drugs by allowing market registration data exclusivity of up to 14.5 years, delaying the onset of cheaper follow-on biologics while inhibiting patent challenges and impeding access to these essential medicines. This is in contrast to the normal five years of market registration data exclusivity currently in place for small-molecule drugs. Alternative legislation proposed by a bi-partisan group from the House and Senate includes more reasonable terms of data exclusivity is now available.

UAEM has argued that this obviously commercially-motivated provision is not in line with the non-profit mission of the university.

Ten million people die every year because they lack access to drugs and medical technologies that already exist. The “Pathway for Biosimilars Acts” will exacerbate the problem by delaying the onset of lower-cost follow-on biologics after patent expiration. The AAU supports its endorsement of the act by referencing pharmaceutical industry claims that the added years of exclusivity are necessary for ensuring cost recovery.

In fact, this claim is at odds with a study¹ 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). Given this conclusion, and the fact that same study also noted that the mean development time for biologics is only 7.4 months longer than that for small molecules, 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. This study acknowledges that “given the nature of patents on biologics, the period of data exclusivity is anticipated to have a key role in determining how quickly follow-on competitors emerge.”

¹ 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>.



“Universities are non-profit, publicly funded institutions, whose mission is to create and disseminate knowledge in the public interest,” said Ethan Guillen, Executive Director of UAEM. “The exclusivity provisions in the bill will restrict access to medicines and violate the core values of the university’s public interest mission. We call the AAU and President Berdahl to bring AAU’s position in line with the university mission.”

Biologics include critical medicines such as insulin and most vaccines, as well as many of the most exciting new treatments that are emerging for conditions such as cancer and autoimmune disease. The additional exclusivity terms in H.R. 1548 will allow drug companies to keep the price of medicines high by delaying the onset of the generic competition that makes medicines affordable to most people.

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About UAEM

Universities Allied for Essential Medicines (UAEM) is a coalition of students at over 40 top research institutions across the United States, Canada, Germany and the United Kingdom. UAEM’s mission is to promote access to medicines for people in developing countries by changing norms and practices around university patenting and licensing, ensuring that university medical research meets the needs of the majority of the world’s population and by empowering students to respond to the access and innovation crisis.