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For Immediate Release

**STUDENT GROUPS AND CONSUMER ADVOCATES DEMAND
WITHDRAWAL OF UNIVERSITY SUPPORT FOR HARMFUL LEGISLATION**

Legislation Would Delay Affordable Medicines in the United States and Abroad

BERKELEY – Today, the American Medical Student Association, Essential Action, and Universities Allied for Essential Medicines (UAEM) joined together in demanding that the Association of American Universities (AAU) withdraw its endorsement of H.R. 1548, the “Pathway for Biosimilars Acts” in a letter sent to AAU President Robert Berdahl.¹ AAU has so far resisted calls to rescind its support of the unjustifiably long twelve years of brand exclusivity permitted by the bill. Such a monopoly period would delay the introduction of generic versions of biologics (called follow-on biologics or biosimilars) which include vaccines as well as life-saving cancer, arthritis, and diabetes drugs, keeping medicine prices high and out of the hands of many consumers in the U.S. and developing countries. The groups are also asking Congress to include a reasonable period of exclusivity that will safeguard affordable access. Small molecule medicines such as Prilosec have exclusivity terms of 5 years.

Economic analyses have repeatedly refuted the AAU’s claim, repeated by the Biotechnology Industry Organization (BIO), that twelve years of exclusivity are needed for sufficient cost recovery to sustain innovation. A recent paper by the Federal Trade Commission estimates that the introduction of follow-on biologics would generate tremendous savings on the \$40.3 billion U.S. consumers spend on biologics each year, some of which cost tens of thousands of dollars per course of treatment.² The extended exclusivity terms in H.R. 1548 and several other legislative proposals would maximize royalties from biologics patents licensed by universities, which are non-profit institutions, at the cost of access.

“AAU’s support for H.R. 1548 truly threatens the core identity of universities as non-profit organizations dedicated to the creation and dissemination of knowledge for the public good,” said Ethan Guillen, Executive Director of UAEM.

Each year the federal government – that is, U.S. taxpayers – provides billions of dollars in research support, accounting for more than 60% of university research budgets. It is unconscionable for federally funded universities, represented by AAU, to so callously

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

² 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>.



obstruct taxpayer access to their life-saving therapeutics. This contradiction is even more poignant at a time when individuals and the federal government struggle to control ballooning healthcare costs. An excessive term of exclusivity will further impede affordable access to critical vaccines, including potentially those for pandemic flu outbreaks. For those ten million people, primarily in developing countries, who die every year because they do not have access to basic medicine, the exclusivity terms in H.R. 1548 will further exacerbate the access gap by delaying the onset of lower-cost follow-on biologics, including critically needed vaccines.

Developing a process for getting biosimilars to market is a critical step to furthering access to affordable medicines. However, in regards to exclusivity terms, universities must show courage in adopting evidence-based stances that benefit society, and not simply act as echo chambers for PhRMA and BIO priorities. Alternate proposals currently being considered include the “Promoting Innovation and Access to Life-Saving Medicine Act” introduced in both the House (H.R. 1427) and the Senate (S.726), proposing a five year exclusivity term, and several proposals for a seven year exclusivity term. Which one of these competing proposals -- 12 to 14 years or five to seven years -- succeeds will shape access to life-saving medicines in the U.S. and abroad and the ability of our health system to control ballooning costs. The time to act is now.

The letter to the AAU is available at: <http://www.essentialmedicine.org/uaem-amsa-and-essential-action-demand-aaU-rescind-support-of-excessive-data-exclusivity/>

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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, the United Kingdom, and Germany. UAEM's mission is to ensure that people in developing countries have access to medicines developed in universities and that university medical research addresses the needs of the majority of the world's population. As an organization which values innovation, we work to empower students to find new ways to improve access to health throughout the world. www.essentialmedicine.org

About the American Medical Student Association

The American Medical Student Association (AMSA), with more than a half-century history of medical student activism, is the oldest and largest independent association of physicians-in-training in the United States. Founded in 1950, AMSA is a student-governed, non-profit organization committed to representing the concerns of physicians-in-training. With more than 62,000 members, including medical and premedical students, residents and practicing physicians, AMSA is committed to improving medical training as well as advancing the profession of medicine. AMSA focuses on four strategic priorities, including advocating for quality, affordable health care for all, global health equity, enriching medicine through diversity and professional integrity, development and student well being. To learn more about AMSA, our strategic priorities, or joining the organization, please visit us online at www.amsa.org/.



About Essential Action

Essential Action is a public health and corporate accountability group located in Washington, DC.