



July 11, 2007

**Association of
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Darrell G. Kirch, M.D.
President

The Honorable Edward M. Kennedy Chairman,
Committee on Health, Education, Labor and Pensions
317 Russell Senate Building
United States Senate
Washington, DC 20510

The Honorable Michael B. Enzi, Ranking Member
Committee on Health, Education, Labor and Pensions
379A Russell Senate Building
United States Senate
Washington, DC 20510

The Honorable Hillary Rodham Clinton,
Committee on Health, Education, Labor and Pensions
476 Russell Senate Building
United States Senate
Washington, DC 20510

The Honorable Orrin G. Hatch
Committee on Health, Education, Labor and Pensions
104 Hart Senate Building
United States Senate
Washington, DC 20510

Dear Mr. Chairman, Ranking Member Enzi, Senator Clinton, and Senator Hatch:

The Association of American Medical Colleges (AAMC) is grateful for your diligent efforts to develop an effective regulatory pathway for the introduction of safe and more affordable follow-on biological products in health care, and recognizes the scientific, economic and political complexities inherent in the task. I write on behalf of the AAMC to comment on the legislation (S. 1695) approved on June 27 by the Health, Education, Labor, and Pensions (HELP) committee. The AAMC represents all 125 U.S. allopathic medical schools, some 400 major teaching hospitals and health systems, and 94 academic societies comprising nearly 100,000 faculty, and our members are awarded nearly 60% of the total extramural funds expended by the National Institutes of Health (NIH) each year.

The biotechnology industry was born from scientific discoveries made in academia, and cutting-edge biologicals continue to be developed from university-based biomedical research, primarily within the academic medical centers represented by the AAMC, and largely funded by NIH. In

July 11, 2007

Page 2

addition, academic medical centers are leading providers of tertiary health care to the American public, and they rank with county and state hospitals as major health care providers to the indigent and other vulnerable populations. Accordingly, the AAMC and its member institutions share the committee's goals to balance incentives and protections for innovative biologicals with improved access to reliable follow-on biologicals that would introduce price competition into this increasingly important sector of the therapeutics market.

We endorse the June 26 comments and recommendations of the Association of American Universities (AAU), which has identified deficiencies in the draft legislation that both our associations believe can be readily remedied. In particular, we strongly concur with the AAU's recommendation that patent owners, not simply licensees, must be given notice of potential challenges from applicants for follow-on biologics (FOB), and that the bill should authorize licensees (BLA holders) that receive access to FOB applications to share information with the licensor, subject as AAU notes, to appropriate confidentiality protections.

Universities own many, if not most, of the underlying patents pertaining to biologics, and they license these patented technologies to commercial firms that are far better able to develop and distribute these products. However, universities must retain the right to enforce their patents. The provisions as currently written, including a 30-day window for third party notification, could deprive universities of timely information about the state of technologies "in play" relating to biosimilars, and could cause universities to lose fundamental property rights simply because of neglect of a licensee or other administrative failure. It cannot be the intent of Congress to advance confiscatory policies where simple requirements for notification, and an extension to a 60-day window, would remediate these concerns.

The draft legislation establishes a reserve fund (p. 41, line 22, to p. 42) based on the estimate of the savings to the Federal Government from the act. The fund would be available to the Secretary to expend on activities authorized under the Public Health Service Act. The AAMC believes strongly that a first priority for allocation of these funds, specifically directed by the legislation, should be to support FDA research and regulatory activities relating to the evaluation and approval of follow-on biologics. We make this recommendation because the restrictions on usage of PDUFA funds enacted in PDUFA II led to the essential dismantlement of the Center for Biologics Evaluation and Research (CBER), which formerly provided the foundation of agency expertise on biologics. The enactment of follow-on biologics legislation will place severe demands on CBER, and the AAMC's recommendation could help to rebuild CBER's capacity in regulatory review and regulatory science.

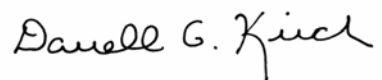
FDA's ability to make consistent, credible judgments about "biosimilarity" and "interchangeability" will necessarily be constrained by the insufficiency of scientific knowledge that must underpin sound regulatory decision making. To obtain independent, expert assessment of the state of this science and identify high priority research needs, AAMC strongly urges that

July 11, 2007
Page 3

the legislation direct the FDA, and provide it with funds, to sponsor a study by the National Academies. The central focus of this study should be to convene a committee of scientific, regulatory, and legal experts to review the pertinent science and make recommendations on how FDA could most effectively and safely proceed in its review of follow-on biologics.

Finally, AAMC understands that the 12-year period of post-market data exclusivity that this bill would provide biologics innovators was introduced as one of several necessary, late compromises by the bill's sponsors. However, we are aware that exactly such a period of extended exclusivity has been a high priority of the biopharma industry for many years, and that if further generalized can have severe adverse consequences for patient accessibility and health care costs. Therefore, we trust that the enactment of this provision in this specific instance will not create a troublesome precedent.

Sincerely,

A handwritten signature in black ink that reads "Darrell G. Kirch". The signature is written in a cursive style with a prominent initial "D".

Darrell G. Kirch, M.D.