

November 5, 2012

Margaret A. Hamburg, M.D.  
Commissioner of Food and Drugs  
Food and Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
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Dear Commissioner Hamburg:

We are writing on behalf of the following higher education associations in consideration of issues raised by the proposed regulatory pathway for the dispute resolution for biosimilar and interchangeable biological products. Our associations include:

- The American Council on Education (ACE), representing the presidents of 1,800 U.S. accredited, degree-granting institutions, which include two- and four-year colleges, private and public universities, and higher education associations.
- The Association of American Medical Colleges (AAMC), a not-for-profit association representing all 141 accredited U.S. medical schools and 17 accredited Canadian Medical Schools; nearly 400 major teaching hospitals and health systems, and 90 academic and scientific societies.
- The Association of American Universities (AAU), an association of 59 U.S. and two Canadian preeminent research universities organized to develop and implement effective national and institutional policies supporting research and scholarship, graduate and undergraduate education, and public service in research universities.
- The Association of Public and Land-grant Universities (APLU), a research and advocacy organization of public research universities, land-grant institutions, and state university systems with member campuses in all 50 states, U.S. territories and the District of Columbia.
- The Association of University Technology Managers (AUTM), a global network of members from more than 350 universities, research institutions, teaching hospitals and government agencies as well as hundreds of companies involved with managing and licensing innovations derived from academic and nonprofit research.
- The Council on Governmental Relations (COGR), an association of 190 U.S. research universities and their affiliated academic medical centers and research institutes that concerns itself with the impact of federal regulations, policies and practices on the performance of research and other sponsored activities conducted at its member institutions.

We write with the concern that under the statutory patent dispute resolution scheme, biosimilars sponsors *can effectively circumvent every patent litigation provision of the statute simply by failing to provide timely notice and access to the reference product sponsor without meaningful consequences, despite the requirement for such notification.* As universities are commonly licensors of biological products, numerous university patents may be affected by biosimilar applications. We do not believe it is appropriate that our

member institutions' rights could be forfeited due to an inadvertent or intentional failure by a biosimilar applicant to notify the reference product sponsor, who in turn can notify the university licensor.

A mandatory yet simple requirement that biosimilar applicants certify their compliance with the notice and access provisions of the statute is warranted. This would ensure that both university licensors and reference product sponsors have adequate opportunity to defend their rights in their inventions. Such a certification mechanism is necessary to ensure notification to the reference product sponsors that an application has been filed and what patents may be implicated. The reference product sponsor then has the ability to assess whether patents in-licensed from a university are implicated and to notify their licensors of possible infringement.

**Accordingly, we urge FDA to take immediate action to impose a certification requirement, which would serve to clarify and enforce the obligations of biosimilar applicants in this regard.** We understand that the Biotechnology Industry Organization (BIO) has raised previously these concerns and has also suggested this proposed response from FDA, and we strongly support this course of action.

Our member institutions appreciate the opportunities that the Food and Drug Administration has provided for stakeholders to provide input on the development of this dispute resolution pathway.

Sincerely,



Molly Corbett Broad  
President  
American Council on Education



Darrell G. Kirch  
President and CEO  
Association of American Medical  
Colleges



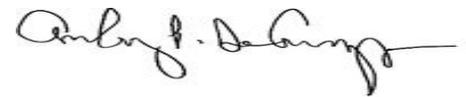
Hunter R. Rawlings III  
President  
Association of American Universities



Peter McPherson  
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Association of Public and Land-grant  
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Todd T. Sherer  
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Anthony P. DeCrappeo  
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