

July 20, 2009

The Honorable Anna Eshoo
205 Cannon House Office Building
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Eshoo:

On behalf of the undersigned state bioscience associations, we are writing to express our support for the Eshoo/Inslee/Barton Amendment creating a pathway for the approval of biosimilars by the Food and Drug Administration when the Energy and Commerce Committee considers H.R. 3200, America's Affordable Health Choices Act.

Biologics are complex medicines manufactured in living systems. They are different and far more complex than most small molecule drugs and include many of the latest breakthrough medical therapies for serious and life-threatening illnesses such as cancer, multiple sclerosis, diabetes, HIV/AIDS, and many serious rare diseases. Any biosimilars approval pathway must recognize that an approved biosimilar will not be a generic copy of a drug, because by definition a biosimilar is similar to, but not the same as, the innovator product.

The Eshoo/Inslee/Barton Amendment to H.R. 3200 merits support because it embodies the strengths of both H.R. 1548, the Eshoo/Inslee/Barton Pathway for Biosimilars Act, as well as the recently-passed Hatch/Enzi/Hagan Amendment at the Senate HELP Committee. As you know, when the HELP Committee considered biosimilars on July 13th, an overwhelming bipartisan majority of senators, including Chairman Kennedy, voted for an amendment which creates a strong approval pathway, and provides 12 years of data exclusivity to ensure continued medical innovation. This amendment passed the HELP Committee by a vote of 16-7, with majority support from both Democrats and Republicans.

The Eshoo/Inslee/Barton Amendment builds upon this success by embodying the bipartisan HELP compromise, while also retaining the important provisions in H.R. 1548 aimed at avoiding patient and provider confusion over biosimilar products and ensuring patent disputes will be resolved prior to the expiry of data exclusivity. We salute you on all your hard work on this very important issue, and look forward to working with you to create the right pathway for biosimilars.

Sincerely,

cc: Congressman Jay Inslee and Congressman Joe Barton

Arizona BioIndustry Association
BayBio
BIOCOM
California Healthcare Institute
Colorado BioScience Association
Connecticut United for Research Excellence (CURE)
Delaware BioScience Association
Bioflorida, Inc.
Georgia Bio
Iowa Biotechnology Association
Illinois Biotechnology Industry Organization
Indiana Health Industry Forum
BioCrossroads (Indiana)
Kentucky BioAlliance
Massachusetts Biotechnology Council
MdBio Division of Technology Council of Maryland
MichBio
LifeScience Alley (Minnesota)
Missouri Biotechnology Association
Montana BioScience Alliance
New Hampshire Bio/Medical Council
North Carolina Biosciences Organization
BioNJ
New York Biotechnology Association
BioOhio
Pennsylvania Bio
South Dakota Biotech Association
Tennessee Biotechnology Association
Texas Healthcare & Bioscience Institute
Utah Technology Council
Virginia Biotechnology Association
Washington Biotechnology & Biomedical Association