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March 19, 2009

The Honorable Anna Eshoo
205 Cannon House Office Bldg
U.S. House of Representatives
Washington, DC 20515

The Honorable Jay Inslee
403 Cannon House Office Bldg
U.S. House of Representatives
Washington, DC 20515

The Honorable Joe Barton
2109 Rayburn House Office Bldg.
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Eshoo, Inslee and Barton:

I am writing on behalf of The ALS Association to express our support for the “Pathway for Biosimilars Act.” This important legislation would promote access to biosimilars while also preserving patient safety and encouraging continued innovation in a field that shows great promise for the development of new treatments for orphan diseases like Lou Gehrig’s disease.

The ALS Association is the only national voluntary health association dedicated solely to finding a treatment and cure for amyotrophic lateral sclerosis (ALS). More commonly known as Lou Gehrig’s disease, ALS is a progressive neurodegenerative disease that erodes a person’s ability to control muscle movement. As the disease advances, people lose the ability to walk, move their arms, talk and even breathe, yet their minds remain sharp; aware of the limitations ALS has imposed on their lives, but powerless to do anything about it. They become trapped inside a body they no longer can control.

While ALS is considered a rare disease, it is among the most common orphan diseases to strike American families. It also is a disease that disproportionately affects our heroes serving in the military, as military veterans are approximately twice as likely to die from ALS as the general public. Unfortunately, for those families living with ALS, there is no cure and the disease is fatal within an average of just two to five years from the time of diagnosis. Moreover, there is no effective treatment currently available for people with ALS.

The hopes of people with ALS – those living today and those yet to be diagnosed – are that medical science will develop and make available new treatments for the disease; treatments that will improve and save their lives. Advances in biotechnology and the development of biologics present the ALS community with new opportunities to bring treatments from the lab to the bedside. Indeed, the ALS scientific community is excited about the promise biologics hold for ALS.

Your legislation would create a new science-based process for the approval of biosimilars, potentially reducing costs and increasing access to treatments for patients. While this is an important goal, people with ALS and other orphan diseases who currently have no treatment options, believe that any biosimilars legislation also must foster innovation and advance the search for breakthrough treatments. This is critical, for legislation that reduces costs without



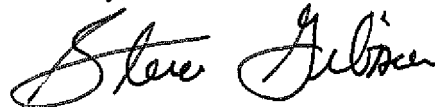
Member National Health Council

promoting new technologies will be of little help to people with ALS whose lives depend on the development of new treatments. In fact, biosimilars legislation that does not appropriately recognize and preserve innovation could limit the development of new treatments for rare diseases like ALS and, therefore, limit hope and the opportunities to access new technologies in the future.

We are pleased that your legislation does not compromise innovation or put cost savings above saving lives. Rather it establishes a pathway that balances these interests and helps to ensure that patients will continue to benefit from advances in medicine – advances that provide hope to people with ALS that a treatment and cure will be found.

The ALS Association applauds your efforts on this important issue and we appreciate your strong support of our cause and your constituents living with ALS. We look forward to working with you and your colleagues to help pass the Pathway for Biosimilars Act during the 111th Congress.

Sincerely,

A handwritten signature in black ink that reads "Steve Gibson". The signature is written in a cursive style with a large, stylized "S" and "G".

Steve Gibson,
Vice President, Government Relations and Public Affairs

