

January 14, 2010

The Honorable Harry Reid  
Majority Leader  
United States Senate  
Washington, DC 20510

The Honorable Nancy Pelosi  
Speaker  
United States House of Representatives  
Washington, DC 20515

Dear Majority Leader Reid and Speaker Pelosi:

We are writing to express our strong support for the inclusion of a regulatory pathway for biosimilars in the final health reform package. Both the House and Senate bills have pathways that will ensure patients have access to lower-cost therapeutics while providing incentives for continued medical research and innovation. These pathways are identical in many ways, though we believe that the House language approved overwhelmingly by the House Energy and Commerce Committee is the better language and should be adopted in the final bill.

Throughout this debate, we have urged Congress to identify the appropriate balance between access, patient safety and the need for continued innovation. Unlike so many of the issues that remain unresolved in health reform, this issue was resolved with the vast majority of Senators and Representatives, both Democrat and Republican, in agreement. In addition, the university community is aligned that 12 years is the appropriate number to ensure continued research. We are at the precipice of an opportunity to provide patients with greater access to lifesaving therapies and cures, so we urge the final health care reform bill contain a strong biosimilars pathway.

The appropriate number of years of data exclusivity is an issue that has been widely debated for many years. Four House Committees and a Senate Committee have held hearings to examine biosimilars and data exclusivity. 150 Members of the House supported legislation that included twelve years of data exclusivity. Amendments that included twelve years of data exclusivity passed overwhelmingly in the House Energy and Commerce Committee (47-11) and Senate HELP Committee (16-7) during the mark-ups of health care reform.

Patients fighting diseases such as cancer, ALS, Alzheimer's disease, HIV/AIDS, autoimmune diseases, neurological disorders and thousands of other untreated or under-treated conditions need access to important therapeutics which depends on scientists to continue research and development aimed at finding new treatments and improved therapies. Amid this larger debate on health reform it has been heartening to see such strong bi-partisan support for the regulatory pathway for biosimilars outlined in the House and Senate bills, and we look forward to working with you in the coming weeks to ensure the House language is adopted as Congress advances a final package.

Thank you for your leadership on this important legislation.

Sincerely,

Alliance for Aging Research  
ALS Therapy Development Institute  
American Association of Neurological Surgeons  
American Association of Orthopaedic Surgeons  
American Autoimmune Related Diseases Association  
American Institute for Medical and Biological Engineering  
American Pain Foundation  
American Urological Association  
APBD Research Foundation  
Association of American Universities  
Californians for Cures  
CANN - Community Access National Network  
Celiac Disease Center at Columbia University  
Children's Tumor Foundation  
Colon Cancer Alliance  
Community Health Charities of America  
Congress of Neurological Surgeons  
Easter Seals  
Foundation for Sarcoidosis Research  
Kids v Cancer  
Lung Cancer Alliance  
Lung Cancer Circle of Hope  
Muscular Dystrophy Association  
National Alliance on Mental Illness  
National Tay-Sachs & Allied Diseases Association, Inc  
Parent Project Muscular Dystrophy  
Parkinson's Action Network  
Parkinson's Disease Foundation  
Prevent Cancer Foundation  
Pulmonary Fibrosis Foundation  
Rehabilitation Institute of Chicago  
Sjögren's Syndrome Foundation  
The ALS Association  
The New York Stem Cell Foundation  
University of North Carolina  
Vanderbilt University Medical Center  
Wisconsin Alumni Research Foundation  
WiSys Technology Foundation