

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