October 14, 2011

The Honorable Barack Obama
President of the United States
The White House
1600 Pennsylvania Avenue, N.W.
Washington, D.C. 20500

Dear Mr. President,

We are writing in regard to your Economic Growth and Deficit Reduction Plan. While we applaud your efforts to address the deficit and recognize that difficult choices must be made, we oppose the proposal to weaken the Biologics Price Competition Act, included in the Affordable Care Act, now the law of our country.

The Kennedy-Eshoo legislation to create a new pathway for biosimilars at the FDA had overwhelming bipartisan and bicameral support. The bill had 149 cosponsors in the House and passed by a vote of 47-11 in the Energy and Commerce Committee. The Senate version was introduced as an amendment in the HELP Committee and passed by a vote of 16-7. Both bodies passed the bill and the legislation was included in the House and the Senate versions of health reform and signed into law by you.

The biotechnology industry in our country is essential to expanding high-value jobs, investing in research and development, and curing, not just treating, some of our most deadly and costly diseases. Medicines developed through biotechnology have the potential to cure cancer, diabetes, Alzheimer's, Parkinson's, multiple sclerosis, arthritis, and many more.

Not surprisingly, biologics can be expensive. With no generic options, many of these remarkable drugs are out of reach for patients. That's why we created a pathway for the approval of biosimilars in health reform. This was the single most significant provision in the Affordable Care Act to lower the cost of drugs in our country. Following in the footsteps of the earlier Hatch-Waxman Act, which ushered in a new era of competition and affordable drugs, the new pathway would for the very first time allow patients access to generic, cheaper versions of biologic drugs.

To establish a new pathway, it was critical to balance the need for patient access with incentives for innovation. Too much protection for an innovator would leave patients with high-costs; too little protection, and innovators would leave the U.S. for friendlier regulatory environments like

the European Union.

The Kennedy-Eshoo *Pathway for Biosimilars* legislation struck that balance by establishing 12-years of data exclusivity for the innovator product. A study by the Congressional Budget Office determined that 11.5-years is the average period of time all drugs are marketed under patent. Because biologics are much more complex and expensive to bring to market than ordinary drugs, they deserve at least an equivalent to small-molecule drugs.

It's important to remember that the pathway established in the Affordable Care Act reduced the years of data exclusivity for biologics from infinity to 12-years. This is a remarkable achievement for patients and payers, reducing the cost of healthcare by $6 billion over the next ten years.

Reducing protection for innovators from 12-years to 7-years will undermine the legislation, leaving Americans in the dust. Biotechnology companies will move overseas where other regulatory environments, like the European Union, recognize the importance of fostering innovation. Just recently the New York Times reported that India and China are investing hundreds of millions into biotechnology (*China and India Making Inroads in Biotech Drugs, 9/18/11*). American patients are the ones who will lose when other countries gain greater access to innovative therapies faster than we do.

Additionally, reducing the years of data exclusivity would force the FDA to contend with biosimilars applications years before the agency planned for, forcing it to reallocate precious resources for reviews.

The Kennedy-Eshoo legislation was endorsed by the Association of American Universities, the governors of five states, and a wide array of more than 70 patient and industry groups, including the AIDS Institute, the ALS Association, and the Alliance for Aging. Twelve years of data exclusivity for biologics is settled United States law. Repeated attempts to weaken this provision, and for a time period with no legitimate basis, is unacceptable.

Sincerely,

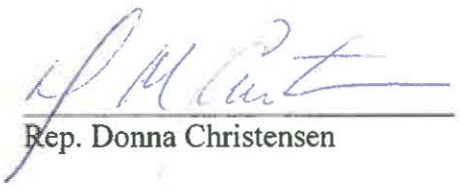
Rep. Anna G. Eshoo

Rep. Joe Barton

Rep. Jay Inslee

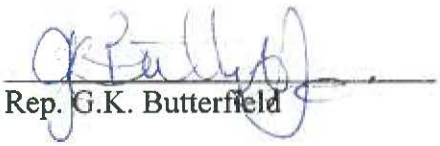
Rep. Leonard Lance

Rep. Joe Pitts



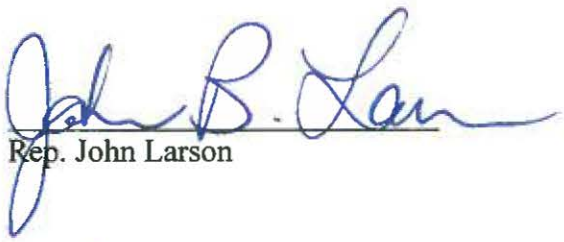
Rep. Donna Christensen

Rep. Gene Green



Rep. G.K. Butterfield

Rep. Joe Courtney



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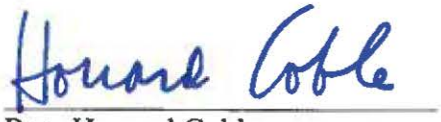

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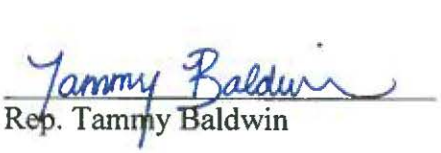

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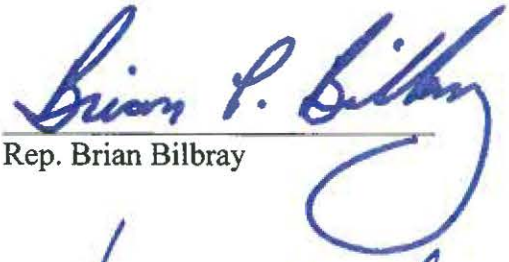
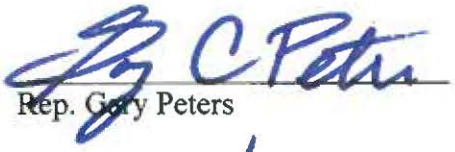


Rep. Brian Bilbray



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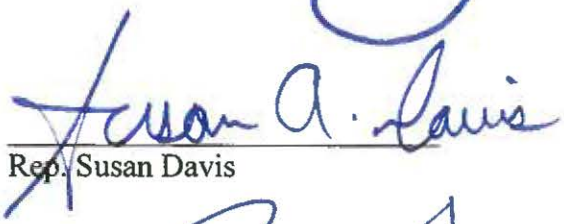

Rep. Susan Davis

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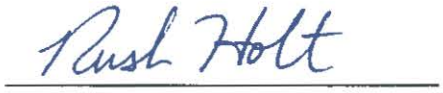
Rep. Robert Latta



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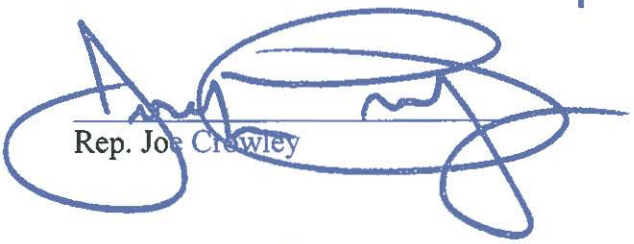
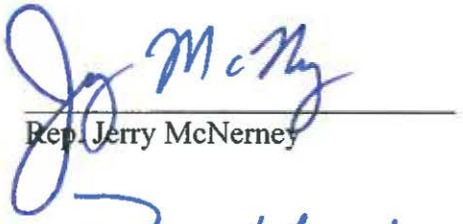

Rep. Joe Crowley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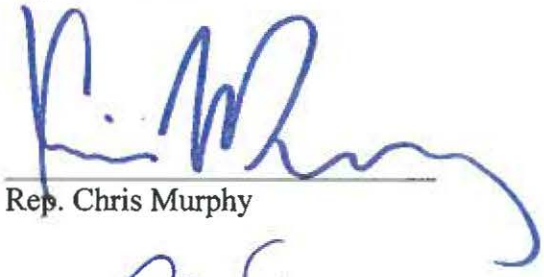
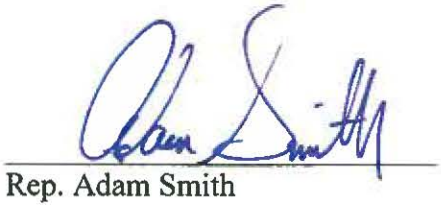
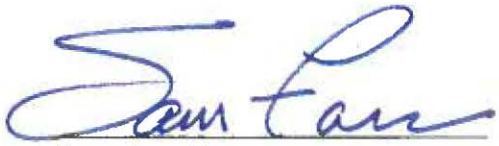

Rep. Chris Murphy


Rep. John Barrow


Rep. Adam Smith


Rep. Chaka Fattah


Rep. Bruce Braley


Rep. Sam Farr


Rep. Mary Bono Back

cc: Rep. John Boehner, Speaker of the House of Representatives
Rep. Eric Cantor, Majority Leader of the House of Representatives
Rep. Nancy Pelosi, Minority Leader of the House of Representatives
Rep. Jeb Hensarling, co-chair, Joint Select Committee on Deficit Reduction
Senator Patty Murray, co-chair, Joint Select Committee on Deficit Reduction
Rep. Chris Van Hollen, Joint Select Committee on Deficit Reduction
Rep. Dave Camp of Michigan, Joint Select Committee on Deficit Reduction
Rep. James Clyburn of South Carolina, Joint Select Committee on Deficit Reduction
Rep. Fred Upton of Michigan, Joint Select Committee on Deficit Reduction
Senator Jon Kyl, Joint Select Committee on Deficit Reduction
Senator John Kerry, Joint Select Committee on Deficit Reduction
Senator Pat Toomey, Joint Select Committee on Deficit Reduction
Senator Max Baucus, Joint Select Committee on Deficit Reduction
Senator Rob Portman, Joint Select Committee on Deficit Reduction
Rep. Xavier Becerra, Joint Select Committee on Deficit Reduction