



March 8, 2012

The Honorable Barack Obama
President of the United States
1600 Pennsylvania Avenue
Washington, D.C. 20510

Dear President Obama,

As a bipartisan group, we recognize that in these difficult financial times we must all work to balance the budget and get our fiscal house in order. However, we must register serious concerns with your Administration's continued attempts to undermine the bipartisan, bicameral, biosimilars law, the Biologics Price Competition Act.

The Biologics Price Competition Act, known as the Pathway for Biosimilars in the House, was the subject of robust discussion before its enactment. The legislation struck an important balance between patient access and innovation, establishing 12 years of data exclusivity for innovator biologics. The twelve year figure was not arbitrary. 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 exclusivity period to their small-molecule counterparts.

The Pathway for Biosimilars Act had 149 cosponsors in the House and passed by a vote of 47-11 in the Energy and Commerce Committee. The Senate version, the Biologics Price Competition *Act*, 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. Very few provisions of health reform enjoyed such broad, bipartisan support, and it should be honored.

Reducing the years of data exclusivity will put the United States at a serious disadvantage to our European counterparts, as their regulatory systems recognize the importance of fostering innovation. Biotechnology companies will move overseas, taking with them high-paying jobs and the innovative spirit that until now has been uniquely American.

The Pathway for Biosimilars Act was endorsed by the Association of American Universities, the governors of five states, and more than 70 patient and industry groups, including the AIDS Institute, the ALS Association, and the Alliance for Aging Research. Twelve years of data exclusivity for biologics has broad bipartisan support from the Congress, and we respectfully request that you refrain from any additional efforts to reduce that protection.

Sincerely,

A handwritten signature in blue ink, appearing to read "M. S. H.", written over a horizontal line.

Joe Courtney

Jodi Spi

David Druin

Wally Harger

Mark

Norina Blackman

Jaron Altman

Ken Schack

Leonard Lance

Ronald C Connolly

Ken Hlg

Jim Wm/Em

Mark W. Amos

Charles Dent

Paul Tiber

Rush Holt

Pete Sei

Phil Chryse

Ernie

Coach The Hon. Rodger

Tim Giffli (AR-027)

Bill Cassidy

Michael H. Merhaye

Gregory Medt

Joe Terry

Allyson Orr

Kent Schneider

John B. Coon

C. Perry

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Patricia Menden

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Art

Loretta Sanchez

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Ly C. Feltner

Gene B. King

Joseph Rowley

John Smith

Tom Salham

Paul

Jim Matteson

Jimmy Baldwin

Joe

Bill Bassett Jr

Joe Bana

Mike Thompson

Robert Gold

John Smith

Mike Ragan

Eric Paulsen

Mary Bono Mack

Sam Furr

Joe Boston

Richard Stone

Howard Cole

Letter to President Obama, House Signatories. March 8, 2012

1. Representative Anna G. Eshoo
2. Representative Joe Courtney
3. Representative Jackie Speier
4. Representative David Dreier
5. Representative Wally Herger
6. Representative Martin Heinrich
7. Representative Marsha Blackburn
8. Representative Jason Altmire
9. Representative Aaron Schock
10. Representative Leonard Lance
11. Representative Gerald Connolly
12. Representative Randy Hultgren
13. Representative Jim McGovern
14. Representative Mark Amodei
15. Representative Charles Dent
16. Representative Laura Richardson
17. Representative Rush Holt
18. Representative Pete Sessions
19. Representative Michael Burgess
20. Representative Ed Towns
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59. Representative Robert Dold
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61. Representative Mike Rogers
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64. Representative Sam Farr
65. Representative Joe Barton
66. Representative Richard Neal
67. Representative Howard Coble