



DUKE UNIVERSITY MEDICAL CENTER

Victor J. Dzau, M.D.
Chancellor for Health Affairs

June 17, 2009

The Honorable Kay Hagan
United States Senate
B40A Dirksen Senate Office Building
Washington, DC 20510

FAX: 202-228-2563

Dear Kay:

I am writing to ask you to consider supporting legislation that we understand Senator Ted Kennedy plans to introduce in the Senate as a companion bill to HR 1548. This bipartisan bill, the Pathway for Biosimilars Act of 2009, recently introduced in the House of Representatives by Reps. Eshoo, Inslee and Barton, would create a mechanism for FDA approval of biosimilars that have been developed by an innovator company. I also ask that you consider incorporating these provisions into any health care legislation that may be considered by the Senate this year.

As you know, North Carolina is home to one of the largest collections of biotechnology companies in the nation. The biotech industry in our state, representing some 450 bio companies, has generated vital revenues and has a total employment impact of over 200,000 jobs. Bio-pharmaceuticals have the potential to make a far greater contribution to the state's economy, but this depends upon a regulatory climate that includes incentives for innovation balanced with the highest standards for patient safety.

HR 1548 establishes a regulatory approval process for biologics, and it offers a balance between patient safety and incentives for product innovation. While this is important for many of the businesses in our region that manufacture such medicines, it also has implications for all North Carolinians who want to safely prevent and treat their diseases with biological products. I hope you will support this legislation.

We are fortunate at Duke Medicine and in North Carolina to have your continued leadership and dedicated service on this and countless other issues. I look forward to continuing to work with you in furthering the goal of stimulating the economy and reducing health care costs.

Sincerely,

A handwritten signature in black ink, appearing to read 'V. Dzau'.

Victor J. Dzau, M.D.



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Victor J. Dzau, M.D.
Chancellor for Health Affairs

June 17, 2009

The Honorable G. K. Butterfield
United States House of Representatives
413 Cannon House Office Building
Washington, DC 20515

FAX: 202-225-3354

Dear Representative Butterfield:

Thank you for cosponsoring HR 1548, the Pathway for Biosimilars Act of 2009, recently introduced in the House of Representatives by Reps. Eshoo, Inslee and Barton. This bipartisan bill would create a mechanism for FDA approval of biosimilars that have been developed by an innovator company.

As you know, North Carolina is home to one of the largest collections of biotechnology companies in the nation. The biotech industry in our state, representing some 450 bio companies, has generated vital revenues and has a total employment impact of over 200,000 jobs. Bio-pharmaceuticals have the potential to make a far greater contribution to the state's economy, but this depends upon a regulatory climate that includes incentives for innovation balanced with the highest standards for patient safety.

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We are fortunate at Duke Medicine and in North Carolina to have your continued leadership and dedicated service on this and countless other issues. I look forward to continuing to work with you in furthering the goal of stimulating the economy and reducing health care costs.

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