COMMONWEALTH of VIRGINIA

Office of the Governor

Timothy M. Kaine
Governor

June 26, 2009

Dear Members of the Virginia Congressional Delegation:

The issue of controlling health care costs is emerging as a major national issue. In support of that goal, I am encouraged by efforts in Congress to strengthen the approval process for biogeneric and biosimilar products and I strongly encourage you to move forward with legislation this year.

Most importantly, we need to provide a competitive environment for biogeneric and biosimilar products that both rewards innovation and provides incentives for generic manufacturers. This will ensure that consumers have timely access to safe and effective generic versions of biological products.

The Food and Drug Administration is the appropriate authority to provide a reasonable and safe regulatory framework to accomplish this goal. Having the FDA approve those biogeneric and biosimilar pharmaceuticals determined to be equivalent to the brand, in terms of safety and effectiveness, will reduce health care costs on individuals, companies and state & local governments. An FDA-driven regulatory pathway will allow the agency to use the same scientific process and the same discretion that it currently has to approve innovative biologics.

The time has come for Congress to move forward on this critical issue. Biogenerics and biosimilar products now are approved in countries around the world and it is time that we bring the benefits from these lower cost products to our citizens. Thank you very much for your consideration.

Sincerely,

Timothy M. Kaine

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